

# **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

***RPA***

November 2008



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European Commission  
Directorate-General Enterprise and Industry

by

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## EXECUTIVE SUMMARY

### Background to Study

A number of boron compounds, principally boric acid, boric oxide, sodium borate and sodium perborate, hereafter referred to as ‘borates’, have recently been proposed for classification as Reprotoxic Category 2 - under the 30<sup>th</sup> and 31<sup>st</sup> *Adaptations to Technical Progress* (ATPs) of Directive 67/548/EEC - and these (potentially) classified borates are the subject of this study. Although the 31<sup>st</sup> ATP has yet to be adopted, the 30<sup>th</sup> ATP (which includes a number of borates) has been adopted and published in the Official Journal. The Commission is, in principle, obliged (within six months of the publication of the classification) to propose appropriate restrictions on their placing on the market and use by consumers as substances or in preparations (above specific concentration limits laid down in the annex of the ATP). Exceptions may be made in cases where there are no unacceptable risks or where the socio-economic benefits outweigh the risks.

RPA has been commissioned by DG Enterprise & Industry to advise on whether such exceptions could be justified for certain uses of the borates. At the start of the study, an approach to the study was agreed that involved a review of the relevant literature and consultation with the relevant industry stakeholders in the EU in order to identify the range of uses for borates. In this study, use has been made of the latest EU classification code for products in order to categorise the diverse uses of borates within a coherent framework. Around twenty different categories of products relevant to borates were identified where these include uses in agriculture and agrochemicals, soaps and detergents, glass and glass products, pharmaceutical preparations, food products and packaging, etc. Table 1 below provides an overview of the main products, applications or industry sectors in which borates are used.

<b>Table 1: Volume of Borates Supplied to Various Products, Applications or Industry Sectors</b>		
<b>Products, Applications or Industry Sectors</b>	<b>Total Volume of Borates Supplied</b>	
	<b>%</b>	<b>Tonnes</b>
Glass and glass products and ceramic	55.8%	334,800
Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	16.8%	100,800
Fertilisers and nitrogen compounds	4.7%	28,200
Chemical and fertiliser minerals	2.4%	14,400
Paper and paper products (including corrugated paper)	1.5%	9,000
Basic pharmaceutical products and preparations	1.4%	8,400
Wood products (e.g. veneer sheets and wood-based panels) - except furniture	1.0%	6,000
Paints, varnishes, coatings, printing ink and mastics	0.5%	3,000
Furniture (e.g. mattresses)	0.1%	600
<b>Other chemicals and chemical products:</b> Various chemical processes including metallurgy, antifreeze, brake fluids, buffers, wallboard, lubricants	8.2%	49,200
<b>Others:</b> Steel slag stabilisation, flame retardance, cellulose insulation, nuclear, electroplating	7.6%	45,600
<b>Total</b>	<b>100%</b>	<b>600,000</b>

Some of these uses are covered by sector-specific legislation which, *inter alia*, is intended to safeguard consumers (and others) from the presence of hazardous chemicals which may include particular borates. Such sector-specific legislation relevant to the borates under study includes:

- the Plant Protection Products Directive;
- the Biocidal Products Directive;
- the Cosmetics Directive;
- the Food Supplements Directive; and
- the Medicinal Products Directive.

These Directives (and associated documents) were reviewed to determine whether specific reference was made to any of the borates under consideration. Where uses were covered by relevant sector-specific legislation, these were explicitly identified and excluded from further consideration.

For the remaining uses, consideration was given to the likely exposure of consumers to the borates present in the product. In some cases, such as detergents, borates may be present as a substance or ingredient in a preparation. As such, there is the potential for a consumer to be directly exposed to the borates present. On the other hand, the borate may be physically/chemically bound into the product such as in ceramics or glass-ware. In these cases, the potential for the consumers to be directly exposed to the borates present is minimal.

This 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 prioritised for further study.

### **Prioritised Uses of Borates (with Potential for Significant Degree of Exposure)**

The assessment of the impacts of potential restrictions and use of possible alternatives focused on three '*prioritised uses*' of borates:

- use in/as a fertiliser mineral;
- use in soaps and detergents, cleaning and polishing preparations; and
- use in other chemical products.

#### **Use as Fertiliser Mineral**

Boron is one of seven elements which are essential to plant growth and classified as 'micro-nutrients'. Boron containing fertilisers are applied to a diverse range of crops and plants (both commercially and by consumers) including fruit, vegetables and forestry (an emerging area for boron, with the development of biomass use). It is also considered critical to many crops (in boron-deficient regions), in particular, oilseed rape (used in the food industry and increasingly for biodiesel production) and sugar beet which are particularly prone to boron deficiency with resultant poor yields and/or diseases. By definition, there are no alternatives to boron when a crop is boron-deficient.

Although the occasional application of boron fertilisers will result in exposure to borates, the level of exposure will be well below the recommended tolerable upper intake level (UL) of 10 mg boron per day. As such, the associated risks to farmers (and other consumers) using boron fertilisers are unlikely to be of serious concern.

Restrictions on the presence of borates in fertilisers placed on the market (for sale to the general public) could result in three possible impacts:

- ***a switch to other borate compounds:*** Of the five boron compounds which may be used as boron fertilisers (as identified in the Fertilisers Regulation), only boric acid and sodium borate are currently covered by the recent classification of borates. Manufacturers of boron-containing fertilisers may, therefore, switch to other borates with minimal socio-economic impacts. However, the risks associated with these ‘alternatives’ would effectively be the same (as the risks are associated with the presence of boron);
- ***an increase in quantities purchased by farmers and consumers:*** Manufacturers of boron-containing fertilisers may reduce the concentrations of borates to below the limits in Annex I of Directive 67/548/EEC. To counter this, farmers would simply add larger quantities of boron fertilisers to their crops, potentially increasing their costs (although this may be absorbed in reduced prices of the ‘diluted’ product); and
- ***loss of market:*** It is estimated that around 42,000 tonnes of borates are currently used in fertilisers. Due to inherent uncertainties in the response of manufacturers and consumers (as well as the extent to which yields may be affected), the exact impact of any potential restrictions cannot be predicted with certainty at this point. However, assuming that downstream users of borates are unable to sell their products to the end-users (or farmers) as a result of the classification, the possible loss of revenue could be in the region of €12 to €60 million with the possibility of wider impacts on specific products and/or lost produce/reduced yield.

Overall, there is a real possibility that any potential restrictions on the use of borates as a fertiliser mineral would result in costs to the industry and consumers with minimal (or no) benefit in terms of risk avoided. In any event, the risks associated with boron fertilisers are unlikely to be of serious concern.

### **Use in Soaps and Detergents**

Boric acid and disodium tetraborate decahydrate are used as enzyme stabilisers in liquid fabric detergents, as well as in a range of cosmetics and oral hygiene products. Sodium perborate (manufactured from boric acid) is used as an oxidizing and bleaching agent in detergent products (and other cleaning products - with possible overlaps with the Biocidal Products Directive).

The use of borates is considered critical in its use to stabilize enzymes in liquid detergents and it is claimed that no suitable alternatives are currently known. However, the concentrations used are below the limits in Annex I of the Directive 67/548/EEC and would, therefore, not be covered by any potential restrictions.

More generally, it is estimated that around 100,000 tonnes of these borates are used in soaps and detergents, as well as in other cleaning products. Over the last five years, the use of sodium perborate in detergent products marketed across Western Europe has decreased by around 80% and sodium perborates have been largely replaced by sodium percarbonates.

Although detergents using sodium perborate would be classified as preparations which are toxic to reproduction (as a result of the 30<sup>th</sup> and 31<sup>st</sup> ATPs), the EU Risk Assessment Report on sodium perborate concludes that consumer exposures to sodium perborate (and, hence, the risks) in detergents are 'negligible'. On this basis, an exception to the standard restriction may be applicable to detergents as there are no unacceptable risks.

In relation to the impact of potential restrictions, the sodium perborate manufacturers indicate that sodium percarbonate delivers a similar technical performance to perborates when used in colder climates. In other words, there are tried and tested alternatives to sodium perborate (for colder climates). However, EU exports of detergents are a major market and may account for 50-70% of production capacity and annual turnover for the EU companies. Although it is possible that the proposed perborate classification (under the yet-to-be adopted 31<sup>st</sup> ATP) may impact on the use of perborates in detergents destined for export from the EU, any reduction in the use of perborates would expect to be counteracted by an increased use of percarbonates. This assumes that suitable technological developments are found to overcome some of the difficulties of handling sodium percarbonate in warmer climates.

Overall, it is considered that any costs relating to the switch-over from sodium perborates to sodium percarbonates would be better considered as business or investment costs relating to a change in the market (since some EU companies have already invested significantly in such changes) - as opposed to a change brought about by the potential restrictions currently being considered. Also, it is the case that any potential restrictions would be targeted at products currently placed on the EU market (with exports being outside the scope of any restrictions). As such, the precise impacts of any restrictions would, therefore, depend on the strategic business response of individual manufacturers (which cannot be predicted at present).

### **Use in Other Chemical Products**

Borates are widely used in industrial fluids such as antifreezes, lubricants, brake fluids, metalworking fluids, water treatment chemicals and fuel additives. The functions of the borates in these fluids include: corrosion inhibition, buffering action, lubrication, stabilisation of thermal oxidation; etc.

These uses mainly relate to industrial products and applications and would, in theory, not be directly affected by any potential restrictions on consumer use. However, some products (which contain borates as substances and preparations) are indeed placed on the market for use by the general public and, as such, would be covered by any potential restrictions. It has also been suggested that the possibility of restrictions could result in the demand for the removal of borates from those products intended for professional use.

The total cost of reformulation for use in lubricants and metal-working fluids alone is estimated (by industry) at around €4 million (as a one-off cost) with recurring costs of around €200 million.



Even if no removal of borates is required from these products, it is indicated that the potential restrictions may destabilise the price of borates, and increases in formulation costs might be expected (even with no change in product composition). For those companies that continue to handle boric acid, they will need to invest in significant changes to their handling and manufacturing procedures as would be required with the new classification. The cost of such changes is not known, but the lubricants industry estimates these to be around €50 million (relating to plant changes) with recurring costs in the form of increased raw material prices expected to be around €20 million.

Since the associated risks to consumers (i.e. non-professional users) are considered to be negligible, it is unlikely that these costs of potential restrictions would be outweighed by the benefits to such consumers.

### **Uses of Borates (with Potential for Possible Exposure)**

Three uses of borates with potential for possible exposure were considered, as follows:

- use of borates in adhesives, paper and pressed panels;
- use in paints and coatings;
- use in mattresses.

For these uses, the intention is that the use of borates is done by professionals. As such, there is no direct risk to consumers from the ‘formulation’ stage (addition of borates). However, the resultant products may be placed on the market for the general public and, thereon, used by consumers in such a way as to result in exposure.

#### **Use of Borates in Adhesives, Paper and Pressed Panels**

For uses in:

- **starch adhesives:** taking the example of a toddler chewing pieces of cardboard containing starch adhesive, the resultant exposure will be well below the tolerable upper intake level of 3 mg B/day recommended by EFSA for toddlers (aged 1-3);
- **cellulose insulation:** as this product is usually applied by professionals and even the keenest DIY (do-it-yourself) person is unlikely to be insulating their house every few years, the associated exposure will be very limited (when considered over a period of years); and
- **veneer sheets and pressed panels:** although consumers would not be involved with the fabrication of veneer sheet and pressed panels, they could be used by consumers in DIY projects. Some exposure could be associated with dust generated when such items are sawn into the desired shape. However, as for the insulation case above, it is very unlikely that this would result in regular or routine exposure.

It is estimated that, in total, around 15,000 tonnes of borates are used in adhesive, paper and pressed panel applications; around 9,000 tonnes are used in paper and paper products and around

6,000 in wood products (veneer sheets and pressed panels). The impacts of potential restrictions on these uses cannot be predicted with certainty at present; however, the analysis indicates that the risk avoided would be negligible.

### **Use in Paints and Coatings**

In paints and coatings, borates are multi-functional coating additives with flame retardant, corrosion inhibiting and buffering properties which may be found in offset printing inks and interior wall paint.

While it is estimated that around 3,000 tonnes of borates are used annually in this sector, it is noted that majority of respondents use other borates not listed in the ATPs and the thresholds mentioned in the ATPs mean that many products will not be affected (due to the low concentrations of borates used). In addition, these products are intended for professional and industrial uses that are covered by the relevant worker safety legislation. In some applications, it is currently unclear whether borates can be substituted (e.g. in intumescent coatings, where they serve a critical life-saving function).

Overall, based on the information provided, the impacts of potential restrictions on the use of borates in the paints and coatings industry may be expected to be minimal.

### **Use in Mattresses**

For use in mattresses, it is concluded that although the consumer product (article) contains borates (boric acid), the application of the borate to the cotton batting will be undertaken by professionals as will the incorporation of the batting into the mattress. Thus, this use of borates is unlikely to be covered by any potential restrictions in any event.

More generally, given the importance of borates as a fire retardant and the low level of associated risks, there would be merit in considering a derogation (should any restrictions be proposed) for the use of borates as (primarily) a fire retardant.

### **Use of Borates in Glass**

Borates are used in a range of glass, glass fibres and glass products where they increase the mechanical strength of glass, as well as their resistance to thermal shock, chemicals and water. It is estimated that around 335,000 tonnes of borates are used in glass and glass products and ceramics. Information provided by APFE (representing glass fibre producers) suggests that over 84,000 tonnes of borates are used by its members to manufacture glass products while EURIMA (representing insulation manufacturers) estimates that around 80,000 tonnes of borates are used in the manufacture of around 3.6 million tonnes of end-product.

In recent years, the boron content in glass has gradually been reduced from 8-10% B<sub>2</sub>O<sub>3</sub> (or 2.5-3% boron) by weight to around 5% (1.5% boron); although the concentrations are much higher in some specialised applications. However, it is considered that the presence of borates in glass

products is extremely unlikely to result in any significant exposure of borates to consumers using such products. Furthermore, since the borates are chemically bound into a crystal lattice of interconnected oxide molecules to form a new substance, glass would not be the subject of restrictions relating to preparations/mixtures containing borates.

In any event, information provided from glass producers and their trade associations indicates that there are currently no known viable alternatives to the use of borates in the manufacture of borosilicate glass or indeed, mineral wool insulation products. Since borates are an integral component for glass fibre manufacturing and boron oxide in the network assures their flexibility and dielectric properties, any potential restrictions on borates would mean that fibre glass products could no longer be manufactured.

### **Impacts on Manufacturers, Importers and Suppliers**

Borates are not mined (significantly) within the EU-27 and the vast majority of borates consumed must be imported into the EU as raw or refined materials or in the form of finished products. Most imports are from Turkey and the USA and the top five importers in the EU are Belgium, Germany, Netherlands, Spain and France.

Based on the information provided, it is estimated that around 600,000 tonnes of borates are supplied to the EU per annum. Although the market appears to have been reasonably stable in the last five years, there has been a reduced demand for sodium perborate (used as bleach in detergents). However demand has increased in most application areas, particularly in agriculture and vitreous (or selected high temperature) applications (such as insulation fibre glass (IFG), borosilicate glass and frits & ceramics).

Assuming that the potential restrictions result in the loss of market in uses accounting for 10-25% of current tonnages in total, the total value of lost sales and revenue is estimated at between **€18 million and €45 million per annum**. The actual economic loss to the EU borates industry would, however, be between **€900,000 and €2.5 million per annum** (where this reflects the actual profit margin after removal of production costs, operational costs, etc.). It is worth noting that most of the importers/suppliers of borates are SMEs which may be impacted more heavily than larger companies. Any wider impacts cannot be stated with certainty at this point.



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# 1. INTRODUCTION

## 1.1 Background to the Study

Directive 67/548/EEC<sup>1</sup> (as amended) describes how all substances present on the European market should be classified and labelled according to European legislation<sup>2</sup>. From time to time, the Directive is updated with additions and revisions through *Adaptations to Technical Progress* (ATP) which are based on proposals from the Commission's Technical Committee on Classification and Labelling of Dangerous Substances.

There have been recent discussions within this Committee concerning the classification and labelling of substances to be presented in the 30<sup>th</sup> and 31<sup>st</sup> ATPs. A number of boron compounds, principally boric acid, boric oxide, sodium borate and sodium perborate, hereafter referred to as 'borates', were proposed for classification as Reprotoxic Category 2 and these (potentially) classified borates are the subject of this study. Although the 31<sup>st</sup> ATP has yet to be adopted or published, the 30<sup>th</sup> ATP (which includes a number of borates) has now been adopted and published in the Official Journal<sup>3</sup>.

Within six months of the classification being published, the Commission is, in principle, obliged to propose restrictions on their placing on the market and use by consumers as substances or in preparations (above specific concentration limits laid down in the annex of the ATP). Hence, in the context of this study, (potential) restrictions refer to any (potential) ban on the placing of borates and preparations containing them on the market for use by the general public, in line with the Marketing and Use Directive (76/769/EEC). Where the concentration of the borates (as a substance or in a given preparation) is below the limits specified in the annex of the ATP, these will not be affected by the 'standard' restrictions. Exceptions to these 'standard' restrictions may be made in cases where there are no unacceptable risks or where the socio-economic benefits outweigh the risks.

RPA has been commissioned by DG Enterprise & Industry to advise on whether such exceptions could be justified for certain uses of the borates. The full (Technical) Specification for the study is attached as Annex 1 and the key tasks have been paraphrased as follows:

- to identify uses of borates in products available to consumers (within the EU);

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<sup>1</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16/08/1967, p1).

<sup>2</sup> This, in turn, determines how preparations should be classified and labelled as set out in Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L200, 30/07/1999, p1).

<sup>3</sup> Commission Directive 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th time, Council Directive 67/548/EEC, (OJ L246, 15/09/2008, p1).

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- to determine whether the exposure/risk associated with such uses is controlled by sector-specific legislation (at an EU Level);
- to assess the degree of exposure (and, hence, risk) associated with those uses (either as substances or in preparations above specified concentrations) not governed by such sector-specific legislation;
- to prioritise those uses with a significant degree of exposure and which are not regulated by sector-specific legislation;
- to identify any national legislation relevant to these prioritised uses;
- to examine in greater detail the risks associated with the prioritised uses and to investigate the potential for restrictions and/or use of alternatives; and
- to assess the impacts (costs and benefits) of any restrictions taking account of the Commission's *Impact Assessment Guidelines* (EC, 2006).

## 1.2 Compounds of Interest

The boron compounds listed in the 30<sup>th</sup> and (proposed) 31<sup>st</sup> ATPs are mainly borates and perborates and, for simplicity, will be referred to hereafter as 'borates'.

The borates include a number of very similar substances which are often referred to by a single name. For example, sodium perborate covers several slightly different substances. As such, the eight entries for the 30<sup>th</sup> ATP and proposed for the 31<sup>st</sup> ATP cover 17 specific substances (each with an individual CAS number) as shown in Table 1.1.

A simple summary sheet of the properties for each of the individual substances is presented in Annex 2. These are not intended to provide definitive views on particular aspects of, for example, toxicological properties but rather to provide readily accessible summaries of relevant and available information on the borates under study.

<b>Table 1.1: Boron Compounds of Interest for this Study (as listed in the adopted 30<sup>th</sup> and proposed 31<sup>st</sup> ATPs)</b>				
<b>ATP Index Number, Entry List and (Proposed) Classification</b>	<b>Name</b>	<b>CAS No.</b>	<b>Conc. Limit*</b>	<b>Annex 2 Reference</b>
005-007-00-2 (30 <sup>th</sup> New Entry) Reprotoxic Category 2	Boric Acid	10043-35-3	C • 5.5%	1
	Boric Acid, Crude Natural, (containing not more than 85% H <sub>3</sub> BO <sub>3</sub> by dry weight)	11113-50-1		2
005-008-00-8 (30 <sup>th</sup> New Entry) Reprotoxic Category 2	Diboron Trioxide; Boric Oxide	1303-86-2	C • 3.1%	3
005-011-00-4 (30 <sup>th</sup> New Entry) Reprotoxic Category 2	Disodium Tetraborate, Anhydrous; Boric Acid, Disodium Salt	1330-43-4	C • 4.5%	4
	Tetraboron Disodium Heptaoxide, Hydrate	12267-73-1		5
	Orthoboric Acid, Sodium Salt	13840-56-7		6



Table 1.1: Boron Compounds of Interest for this Study (as listed in the adopted 30 <sup>th</sup> and proposed 31 <sup>st</sup> ATPs)				
ATP Index Number, Entry List and (Proposed) Classification	Name	CAS No.	Conc. Limit*	Annex 2 Reference
005-011-01-1 (30 <sup>th</sup> New Entry) Reprotoxic Category 2	Disodium Tetraborate Decahydrate; Borax Decahydrate	1303-96-4	C • 8.5%	7
005-011-02-9 (30 <sup>th</sup> New Entry) Reprotoxic Category 2	Disodium Tetraborate Pentahydrate; Borax Pentahydrate	12179-04-3	C • 6.5%	8
005-006-00-7 (31 <sup>st</sup> Revised Entry) Reprotoxic Category 2 Mutagenic Category 3	Dibutyltin Hydrogen Borate	75113-37-0	-	9**
005-017-00-7 (31 <sup>st</sup> New Entry) Reprotoxic Category 2 Reprotoxic Category 3	Sodium Perborate	15120-21-5	6.5% • C< 9%	10
	Perboric Acid, Sodium Salt	11138-47-9		11
	Perboric Acid, Sodium Salt, Monohydrate	12040-72-1		12***
	Sodium Peroxometaborate	7632-04-4		13
	Perboric Acid (HBO(O <sub>2</sub> )), Sodium Salt, Monohydrate	10332-33-9		14
	Sodium Peroxoborate	Not specified		-
005-018-00-2 (31 <sup>st</sup> New Entry) Reprotoxic Category 2 Reprotoxic Category 3	Perboric Acid (H <sub>3</sub> BO <sub>2</sub> (O <sub>2</sub> )), Monosodium Salt, Trihydrate	13517-20-9	10% • C< 14%	15
	Perboric Acid, Sodium Salt, Tetrahydrate	37244-98-7		16
	Perboric Acid (HBO(O <sub>2</sub> )), Sodium Salt, Tetrahydrate	10486-00-7		17
	Sodium Peroxoborate Hexahydrate (containing <0.1 % (w/w) of particles with an aerodynamic diameter of below 50 •m)	Not specified		-
Notes (further details relating to the classification can be found in Annex 1)				
* Conc. Limit (C) represents the lowest concentration of borates present in a preparation which will be classified as an R60-61 or R61				
** Already banned in concentrations >0.1%(Directive 89/677/EEC)				
*** CAS Number unknown but probably identical to CAS 10332-33-9				

It is important to note that there are many other similar boron compounds which may be used for similar purposes as those compounds listed in Table 1.1 (e.g. where the required functionality is associated with the presence of the boron). As such, switching from one particular listed borate to a similar but unlisted borate would meet the regulatory requirements but would not significantly change the Reprotoxic risks (as these risks are associated with the presence of boron).

## 1.3 Approach to the Study

A kick-off meeting for this project was held with the Commission in December 2007. This involved identification of key contacts within the borates industry, as well as known sources of information. It also served to further clarify the intended scope of the study.

At the start of the Project, an approach to the study was agreed that involved a review of the relevant literature and consultation with the relevant industry stakeholders in the EU in order to identify the range of uses for borates. In this study, use has been made of the latest EU classification code<sup>4</sup> for products in order to categorise the diverse uses of borates within a coherent framework.

Some of the uses are covered by sector-specific legislation which is intended to safeguard consumers (and others) from the presence of hazardous chemicals which may include particular borates. The relevant legislation was, therefore, reviewed to determine whether specific reference was made to any of the borates under consideration. Where uses were covered by relevant sector-specific legislation, these were explicitly identified and excluded from further consideration.

For the remaining uses, consideration was given to the likely exposure of consumers to the borates present in the product. In some cases, such as detergents, borates may be present as an ingredient in a preparation. As such, there is the potential for a consumer to be directly exposed to the borates present. On the other hand, the borate may be physically/chemically bound into the product such as in ceramics or glass-ware. In these cases, the potential for the consumers to be directly exposed to the borates present is minimal. Note that the risk assessment undertaken for this study has focussed on preparations containing borates at or above the specific concentration limits laid down in the annex of the ATP.

This approach enabled a short-list of uses of borates to be drawn up for which:

- the uses are not covered by sector-specific legislation; and
- there is the potential for consumers to be exposed to borates.

An interim report was submitted for this project in March 2008 setting out the findings of the above steps.

In April 2008, manufacturers, importers, suppliers and downstream users of borates, products containing borates and their alternatives were asked for their views on:

- the current role and importance of borates in its various products and applications; and

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<sup>4</sup> Specifically, Eurostat (2008): *Statistical Classification of Products by Activity in the European Economic Community, 2008 Version* as implemented by **Regulation (EC) No 451/2008 of the European Parliament and of the Council of 23 April 2008 establishing a new statistical classification of products by activity (CPA) and repealing Council Regulation (EEC) No 3696/93** (OJ L145, 04/06/2008, p65)

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- the suitability (in terms of their technical, environmental and health aspects) of various alternatives to borates in these applications.

The questionnaire that was used during consultation did not request information on exposure scenarios and other toxicological aspects relating to borates (as this had already been addressed in the Interim Report submitted in March 2008). However, industry did provide such information, where available, and where such information has been found to be relevant, it has been taken into account in this report.

Questionnaires were sent by email to the stakeholders and responses were invited in either written or electronic form. Based on the responses to the questionnaire, follow-up through direct contact was undertaken with a number of respondents (between April and June 2008). The reasons for such follow-up included:

- the wish to gather information outside the scope of the questionnaire;
- to obtain clarification of questionnaire responses; or
- to discuss particular aspects in more detail.

Consultation with companies for this study has relied mainly on contacts with the relevant industry associations, although in some cases, individual companies were approached directly (particularly if issues of confidentiality were involved). A listing of the organisations and companies which provided information for this study is included in Annex 3.

We also attended a workshop organised by the European Borates Association on 24 June, 2008 in Brussels where industry provided and discussed information on the various uses and markets for borates and their alternatives.

This Final Report presents the findings of the study and the conclusions and recommendations for action at the EU level.

In the context of this study, (potential) restrictions refer to the (potential) ban on the placing of borates and preparations containing them on the market for use by the general public, in line with the Marketing and Use Directive (76/769/EEC).

## **1.4 Structure of the Report**

The remaining sections of this report are organised as follows:

- Section 2 provides an **overview of the borates industry** (manufacture, import and export);
- Section 3 identifies the various **uses of borates by consumers** within the EU;
- Section 4 determines whether the exposure/risk associated with such uses is controlled by **sector-specific legislation** (at an EU Level);

- Section 5 provides an **assessment of the associated degree of exposure** (and, hence, risk) for those uses not governed by such sector-specific legislation,). Those uses with a significant degree of exposure and which are not regulated by sector-specific legislation were then prioritised for further study;
- Section 6 assesses the **impacts (costs and benefits) of any restrictions** on the prioritised uses of borates, taking into account the risks identified and the potential for use of alternatives; and
- Section 7 provides the study **conclusions**.

There are also five Annexes to the Report:

- Annex 1 presents the **Project Specifications** as agreed between RPA and the European Commission;
- Annex 2 provides a simple **summary sheet of the properties** for each of the individual substances;
- Annex 3 provides a **List of Consultees** for this study;
- Annex 4 provides further information on the use of **borates in glass**; and
- Annex 5 provides further information on the use of **borates in other applications**.

## 2. OVERVIEW OF THE BORATES INDUSTRY

### 2.1 Mining of Borates

#### 2.1.1 Minerals

The primary sources of borates are four minerals:

- tincal ('natural borax') ( $\text{Na}_2\text{O} \cdot 2\text{B}_2\text{O}_3 \cdot 10\text{H}_2\text{O}$ );
- kernite ( $\text{Na}_2\text{O} \cdot 2\text{B}_2\text{O}_3 \cdot 4\text{H}_2\text{O}$ );
- colemanite ( $2\text{CaO} \cdot 3\text{B}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ ); and
- ulexite ( $\text{Na}_2\text{O} \cdot 2\text{CaO} \cdot 5\text{B}_2\text{O}_3 \cdot 16\text{H}_2\text{O}$ ).

Globally, mining of these minerals is dominated by Turkey and the USA with lesser contributions from Argentina, Chile, Russia and China as shown in Table 2.1. In recent years, there has been a steady growth in mineral production to the current level of over five million tonnes per annum (with an associated value of the order of €1bn).

<b>Table 2.1: World Production of Boron Mineral Ore by Country 2002-06 (x 1000 tonnes/annum)</b>					
<b>Country</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>
Turkey	1,368	1,377	1,697	2,200	2,500
United States	1,050	1,150	1,210	1,150	1,150 (est)
Argentina	516	512	821	633	650
Chile	431	401	594	461	460
Russia	1,000	1,000	500	400	400
China	145	130	135	140	145
Bolivia	40	110	68	63	60
Kazakhstan	30	30	30	30	30
Peru	7	9	10	10	10
<b>World Total</b>	<b>4,580</b>	<b>4,720</b>	<b>5,070</b>	<b>5,090</b>	<b>5,410</b>
<i>Source: USGS (2007)</i>					

#### *Turkey*

The Turkish borate industry is dominated by Eti Mine Works which operates the main mines at Kirka (for tincal), Bigadic (for colemanite and ulexite), Emet (for colemanite) and Kestelek (for colemanite) (Helvacı & Alonso, 2000).

#### *USA*

The US borates industry is dominated by Rio Tinto Borax with extensive mining at Boron (California) for, primarily, tincal and kernite.

## *EU*

Since few borates are produced in the EU, the vast majority (over 95%) of borates are imported - mainly from Turkey and the USA. Although Larderello in Italy was the sole source of boric acid in the mid-19<sup>th</sup> century<sup>5</sup>, the current contribution to the EU borates supply is very small.

### **2.1.2 Refined Mineral Products**

The major companies in Turkey and the USA sell a limited range of bulk borate products including refined mineral products such as:

- disodium tetraborate pentahydrate (borax pentahydrate) is the main refined mineral product (as *Etibor-48* from Eti Mines and *Neobor* from Rio Tinto) with 480,000 tpa from Kirka, Turkey;
- boric acid is the second most common refined mineral product (as *Optibor* from Rio Tinto) with 85,000 tpa from Bandirma, Turkey and a further 100,000 tpa from Emet, Turkey (from 2003). Boric oxide (anhydrous boric acid) is also provided as bulk material;
- disodium tetraborate pentahydrate/decahydrate (borax penta- and deca-hydrate) - 55,000 tpa (combined) from Bandirma Borax plant in Turkey;
- ground colemanite - 90,000 tpa from Bigadic, Turkey; and
- sodium tetraborate, anhydrous (anhydrous borax) - plant capacity 60,000 tpa at Kirka, Turkey (but not operational at present).

The associated product prices (from December 2006) (USGS, 2007) are:

- €680 - €705 per tonne of anhydrous borax;
- €260 - €290 per tonne of borax decahydrate;
- €305 - €320 per tonne of borax pentahydrate; and
- €680 - €710 per tonne of boric acid.

## **2.2 Consumption, Imports and Exports**

The global borate production is over 5 million t/yr (equivalent to around 2.3 million t B<sub>2</sub>O<sub>3</sub> per year or over 700,000 tB/yr). It might be expected that the EU-27 consumes about 20% of the global production which would lead to consumption figures of the order of 1 million, 460,000 and 140,000 t/yr expressed as ore, B<sub>2</sub>O<sub>3</sub> and B respectively.

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<sup>5</sup> The boric acid was derived from geothermal springs leading to the establishment of the company Società Chimica Larderello which still produces borates today. Larderello was also the world's first geothermal power station (Dickson & Fanelli, 2004).

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Since borates are not mined (significantly) within the EU-27, it is clear that the vast majority of borates consumed must be imported into the EU as raw or refined materials or in the form of finished products. Although there is not a single authoritative source of such data for the EU, it is possible to locate some data.

For this study, international trade data based on HS Code 2840 have been reviewed (BAC, 2007). Under the *Harmonized Commodity Description and Coding System* (HS) maintained by the World Customs Organization, HS Code 2840 and associated subdivisions are derived as follows:

**28 Inorganic Chemicals; Organic or Inorganic Compounds of Precious Metals, of Rare-Earth Metals, of Radioactive Elements or of Isotopes**

**2840 Borates; Peroxoborates (Perborates)**

**2840.1 Disodium Tetraborate (Refined Borax)**

**2840.11 Anhydrous Disodium Tetraborate (Refined Borax)**

**2840.19 Other Disodium Tetraborate (Refined Borax)**

**2840.20 Other Borates**

**2840.30 Peroxoborates (Perborates)**

Although there are considerable uncertainties over the robustness of such trade data, the data do provide an indication of which EU countries are most active in the import and export of borates (as covered by HS Code 2840).

As would be expected, most imports are from Turkey and, to a lesser extent, from the USA. Most of the remainder comprises intra-EU trade. The countries with the largest imports would be expected to have either processing facilities and/or to be a 'gateway' for imports to neighbouring countries (as is the case for the Netherlands). The top five importers are listed in Table 2.2.

Table 2.2: Imports of Borates to EU-27 (HS Code 2840)					
Country	Total Imports (t/year)	% Imports from Turkey	% Imports from USA	% Imports from EU	% Imports from Elsewhere
Belgium	126,433	81%	2%	16%	0%
Germany	100,791	40%	53%	5%	2%
Netherlands	89,218	82%	0%	18%	1%
Spain	56,839	32%	66%	2%	0%
France	42,882	25%	39%	35%	1%
Top 5 Importers	416,163	59%	27%	14%	1%
EU-27	615,323	59%	20%		
Top 5 as % of EU-27	68%	88%	67%		
Source: BAC (2007)					
Note: Although data quantities cover a range of borates (from raw materials to refined products), the figures are of a similar magnitude to the suggested consumption figures presented above (including that of 460,000 t/yr expressed as B <sub>2</sub> O <sub>3</sub> ).					
As figures have been rounded to nearest % value, summation may not give 100% in all cases.					

The top five importers re-appear as the top five exporters (albeit in a different order). As would be expected, the overall level of imports exceeds the level of exports and the value of exports (€0.32 per kg) is slightly greater than that for imports (€0.27 per kg). However, the case of the Netherlands indicates some of the associated uncertainties in that, according to the data presented, it exports more than it imports (which is not possible as the Netherlands does not mine borates).

Although most exports from EU countries are to nearby countries, detailed inspection of the figures for the top five exporters suggests that this is not exclusively the case - as is shown in Table 2.3. However, once again this picture may have been distorted by uncertainties in the data and their reporting.

Table 2.3: Exports of Borates from EU-27 (HS Code 2840)			
Country	Total Exports (t/year)	Exports as % of Imports	Comment
Netherlands	99,790	112%	
Belgium	75,023	59%	Belgium's 4 <sup>th</sup> largest export market for borates is Cote d'Ivoire
Germany	17,084	17%	
Spain	12,654	22%	Spain's 3 <sup>rd</sup> largest export market for borates is Cote d'Ivoire
France	5,478	13%	France's 2 <sup>nd</sup> largest export market (in value terms) for borates is the USA
Top 5 Exporters	210,029	50%	
EU-27	227,293	37%	
Top 5 as % of EU-27	92%	-	
Source: BAC (2007)			



### **3. USES OF BORATES**

#### **3.1 Classification of Uses**

Within the EU, there are numerous systems in use for the classification of trade, products and activities. For the purposes of this study, use has been made of the *Statistical Classification of Products by Activity in the European Economic Community, 2008 Version* (Eurostat, 2008), hereafter referred to as CPA 2008<sup>6</sup>.

Under CPA 2008, products are grouped at several levels as illustrated below using the example of a laundry detergent:

##### **C Manufactured Products**

##### **20 Chemicals and chemical products**

##### **20.4 Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations**

##### **20.41 Soap and detergents, cleaning and polishing preparations**

##### **20.41.3 Soap, washing and cleaning preparations**

##### **20.41.32 Detergents and washing preparations**

CPA 2008 has been used to provide a framework for presenting the identified uses of borates and a summary of the uses of borates is presented in Table 3.1.

To ensure that CPA 2008 references are not confused with references to other sections of the report, the initial letter from the CPA Code (B or C) has been included. So, for example, C20.41 refers to the CPA 2008 classification for: *Soap and detergents, cleaning and polishing preparations*.

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<sup>6</sup> While the CPA classification is based on ‘products by activity’, there is another similar classification of ‘economic activities’ (NACE). Where classifications overlap, the CPA 2008 and the NACE (Revision 2) codes are now the same. CPA 2008, NACE (Revision 2) and PRODCOM (products) form an integrated EU classification system (see [circa.europa.eu/irc/dsis/nacecpacon/info/data/en/index.htm](http://circa.europa.eu/irc/dsis/nacecpacon/info/data/en/index.htm)).

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Table 3.1: Borates in Products by Section and 2, 3 and 4 Digit CPA 2008 Classification			
A	PRODUCTS OF AGRICULTURE, FORESTRY AND FISHING - <i>Not relevant</i>		
B	MINING AND QUARRYING		
	05	Coal and lignite	
	06	Crude petroleum and natural gas	
	07	Metal ores	
	08	Other mining and quarrying products	
		08.9	Mining and quarrying products n.e.c. ( <i>n.e.c.</i> = <i>not elsewhere classified</i> )
		08.91	Chemical and fertiliser minerals
	09	Mining support services	
C	MANUFACTURED PRODUCTS		
	10	Food products	
		10.8	Other food products
		10.86	Homogenised food preparations and dietetic food
	11	Beverages	
	12	Tobacco products	
	13	Textiles	
		13.2	Woven textiles
		13.20	Woven textiles
	14	Wearing apparel	
	15	Leather and related products	
	16	Wood and of products of wood and cork, except furniture; articles of straw and plaiting materials	
		16.2	Products of wood, cork, straw and plaiting materials
		16.21	Veneer sheets and wood-based panels
	17	Paper and paper products	
		17.1	Pulp, paper and paperboard
		17.11	Pulp
		17.2	Articles of paper and paperboard
		17.21	Corrugated paper and paperboard and containers of paper and paperboard
	18	Printing and recording services	
	19	Coke and refined petroleum products	
	20	Chemicals and chemical products	
		20.1	Basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms
		20.13	Other inorganic basic chemicals
		20.15	Fertilisers and nitrogen compounds
		20.2	Pesticides and other agrochemical products
		20.20	Pesticides and other agrochemical products
		20.3	Paints, varnishes and similar coatings, printing ink and mastics
		20.30	Paints, varnishes and similar coatings, printing ink and mastics
		20.4	Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations
		20.41	Soap and detergents, cleaning and polishing preparations
		20.42	Perfumes and toilet preparations
		20.5	Other chemical products
		20.51	Explosives
		20.59	Other chemical products n.e.c.
	21	Basic pharmaceutical products and pharmaceutical preparations	
		21.2	Pharmaceutical preparations
		21.20	Pharmaceutical preparations
	22	Rubber and plastics products	
	23	Other non-metallic mineral products	
		23.1	Glass and glass products
		23.13	Hollow glass

Table 3.1: Borates in Products by Section and 2, 3 and 4 Digit CPA 2008 Classification			
		23.14	Glass fibres
		23.19	Other processed glass, including technical glassware
	23.2	Refractory products	
		23.20	Refractory products
	23.3	Clay building materials	
		23.31	Ceramic tiles and flags
	23.4	Other porcelain and ceramic products	
		23.41	Ceramic household and ornamental articles
		23.42	Ceramic sanitary fixtures
		23.43	Ceramic insulators and insulating fittings
		23.44	Other technical ceramic products
	24	Basic metals	
		24.1	Basic iron and steel and ferro-alloys
		24.10	Basic iron and steel and ferro-alloys
		24.4	Basic precious and other non-ferrous metals
		24.42	Aluminium
		24.43	Lead, zinc and tin
		24.44	Copper
		24.45	Other non-ferrous metal
		24.46	Processed nuclear fuel
	25	Fabricated metal products, except machinery and equipment	
		25.3	Steam generators, except central heating hot water boilers
		25.30	Steam generators, except central heating hot water boilers
		<i>Boron alloys likely to be used in other metal products</i>	
	26	Computer, electronic and optical products	
		26.1	Electronic components and boards
		26.11	Electronic components
		26.2	Computers and peripheral equipment
		26.20	Computers and peripheral equipment
		26.5	Measuring, testing and navigating equipment; watches and clocks
		26.51	Measuring, testing and navigating equipment
		26.7	Optical instruments and photographic equipment
		26.70	Optical instruments and photographic equipment
	27	Electrical equipment	
		27.4	Electric lighting equipment
		27.40	Electric lighting equipment
		27.5	Domestic appliances
		27.51	Electric domestic appliances
		27.52	Non-electric domestic appliances
		27.9	Other electrical equipment
		27.90	Other electrical equipment
	28	Machinery and equipment n.e.c.	
		28.2	Other general-purpose machinery
		28.29	Other general-purpose machinery n.e.c.
	29	Motor vehicles, trailers and semi-trailers	
		<i>Boron-containing products such as airbags and alloys used in vehicles</i>	
	30	Other transport equipment	
		<i>As for motor vehicles above</i>	
	31	Furniture	
		31.0	Furniture
		31.03	Mattresses
	32	Other manufactured goods	

## **3.2 Description of Uses of Borates**

### **3.2.1 Mineral and quarrying products n.e.c.<sup>7</sup> (B08.9)**

Boron is one of the seven elements<sup>8</sup> which are essential to plant growth and classified as 'micro-nutrients'. As such, boron containing fertilisers (classified under B08.91 - chemical and fertiliser minerals) are applied to a diverse range of crops and plants (both commercially and by consumers). According to the Fertilisers Regulation<sup>9</sup>, boron fertilisers include boric acid, sodium borate, calcium borate and boron ethanol amine; however, only boric acid and sodium borate are currently covered by the recent classification of borates. This use is discussed in more detail in Section 6.3.

### **3.2.2 Other food products (C10.8)**

Natural levels of borates are found in many food products (and beverages). Boron (in various forms) is widely available as a diet supplement (classification C10.86) with claims for healthy bones and other life/health improvements.

### **3.2.3 Woven textiles (C13.2) & Glass fibres (C23.14)**

One of the largest uses of borates in Europe is in insulation and textile fibreglass. Where the fibreglass is woven, it is classified under C13.2, otherwise it is classified under C23.14 (glass fibres). In both insulation and textile fibre glass, borates act as a powerful flux and lower glass batch melting temperatures. They also control the relationship between temperature, viscosity and surface tension to create optimal glass fiberisation (IMA, 2008). Borates may also be used as fire retardants in woven textiles.

Fibre-glass (also known as E-glass) dates back to the 1940s and the normal boron feedstock is boric acid. Most fibre-glass is combined with plastics and resins to form GRP (glass reinforced plastic) which is used across a very wide range of products (Borax, 1998). In recent years, the boron content has gradually been reduced from 8-10% B<sub>2</sub>O<sub>3</sub> by weight to around 5%. Furthermore, boron-free glass fibres are now available<sup>10</sup>.

Recent figures suggest a glass fibre production of nearly 800,000 t/year (CPIV, 2008) which at 5-10% B<sub>2</sub>O<sub>3</sub> suggests a B<sub>2</sub>O<sub>3</sub> usage of around 50,000 t/year.

This use is discussed in more detail in Annex 4.

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<sup>7</sup> Not elsewhere classified.

<sup>8</sup> The seven elements are boron, chlorine, copper, iron, manganese, molybdenum and zinc.

<sup>9</sup> **Regulation (EC) No. 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers**, (OJ L304, 21/11/2003, p1).

<sup>10</sup> Boron-free glass fibres include those for both general purposes (such as *Advantex*) and special purposes (see, for example, Wallenberger *et al*, 2001 and APFE, 2003). In these boron-free glass fibres, it appears to be the case that rather than the boron being replaced with another additive, the boron-free glass is produced from a different mix of oxides under different heat conditions.

### **3.2.4 Products of wood, cork, straw and plaiting materials (C16.2)**

Borates may be used as fire retardants in various ‘pressed’ boards (C16.21, including fibreboard - C16.21.14). Further details on this usage are presented in Annex 5.

### **3.2.5 Pulp (C17.11)**

Borates are used in cellulose insulation material primarily to provide fire resistance (but the borates will also provide some protection against mould and insects). In this application, shredded newspaper is mixed with, perhaps, 15% borates and the resulting product is blown into attics and in cavity walls (by professionals). Such products have been considered to be *pulps of wood or other fibrous cellulosic material* (C17.11.1). Further details on this usage are presented in Annex 5.

### **3.2.6 Corrugated paper and paperboard and containers of paper and paperboard (C17.21)**

Borates (as boric acid or borax pentahydrate) are used in various corrugated and other paperboard products as an adhesive and/or as a flame retardant. Further details on this usage are presented in Annex 5.

### **3.2.7 Basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms (C20.1)**

Borates (and perborates) are listed with ‘other inorganic basic chemicals’ (C20.13) under the classification C20.13.62.

### **3.2.8 Pesticides and other agrochemical products (C20.2)**

Borates have long been used as biocides with particular uses as insecticides (C20.20.11) and fungicides (C20.20.15). Borates (borax products) have been found to be particularly effective for timber treatment (for dry rot).

Nevertheless (as discussed further in Section 3.3.3), it is worth noting that, due to the implementation of Directive 98/8/EC on Biocidal Products, several borates are no longer authorised (as of 31 December 2007) for use in specific types of biocides including the use of disodium tetraborate in anhydrous (CAS 1330-43-4) and decahydrate (CAS 1303-96-4) forms) in *insecticides, acaricides and products to control other arthropods*.

### **3.2.9 Paints, varnishes and similar coatings, printing ink and mastics (C20.3)**

Borates are used in the paints and coatings industry in a number of products and applications including:

- use in frits and glazes for ceramics<sup>11</sup> (as used in floor/wall tiles, housewares, etc. - as discussed further in sub-section 3.2.15);
- use in hard-wearing enamels (as used on baths, stoves, washing machines, etc. (which would be covered by C27.51/52 ‘domestic appliances’)) and other ‘refractory paints’;
- use in steel works (coil coatings) and in body shops (e.g. car refinish painting);
- use as specialist driers in offset printing inks;
- use in interior wall paint; and
- use in marine, protective, yacht and aerospace coating applications for fire retardance.

This use is discussed in more detail in Annex 5

### **3.2.10 Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations (C20.4)**

The EU consumption of detergents (mainly laundry detergents) has been estimated as six million tones per year (RPA, 2006). Modern laundry detergents (classified under C20.41) typically contain 15% sodium perborate or, increasingly, sodium percarbonate. Although, historically, the largest consumption of the borates under study would have been as sodium perborate, this is no longer the case as manufacturers switch to sodium percarbonate.

Assuming 80% detergents use bleaches and 40% still use perborate, the consumption of sodium perborate in detergents would be expected<sup>12</sup> to be of the order of 290,000 tpa (equivalent to about 25,000 tB/year). These figures are lower than that of 421,600 tpa provided for the EU (albeit for 1997<sup>13</sup>) in the EU Risk Assessment Report (Umweltbundesamt, 2007).

Boric acid ( $\text{H}_3\text{BO}_3$ ) and disodium tetraborate decahydrate ( $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$ ) are used as enzyme stabilisers in liquid fabric detergents. HERA (2005) estimates a total consumption of about 930 tB/year which for boric acid and disodium tetraborate decahydrate combined is equivalent to around 6,500 t/year.

Boric acid and disodium tetraborate decahydrate are also used in a range of cosmetics and oral hygiene products (classification C20.42).

This use is discussed in more detail in Section 6.4.

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<sup>11</sup> One of the largest uses of borates in Europe is in frits and glazes for ceramics - which are classified under sub-section C20.30.21 (*prepared pigments, opacifiers and colours, vitrifiable enamels and glazes, engobes, liquid lustres and the like; glass frit*).

<sup>12</sup> However, as discussed further in Section 6.4, consultation responses suggest an even lower proportion of perborates at perhaps 15%.

<sup>13</sup> The figure of 421,600 is drawn from the industry risk assessment of sodium perborate report prepared under the HERA programme (HERA, 2002).

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### **3.2.11 Other chemical products (C20.5)**

Borates are well established and widely used in the manufacture of industrial fluids such as antifreezes, lubricants, brake fluids, metalworking fluids, water treatment chemicals and fuel additives (classification C20.59.4). Borates' function in these fluids include: corrosion inhibition, buffering action, freezing point reduction, boiling point elevation, lubrication, stabilization of thermal oxidation (e.g. during metal surface working (see sub-section 3.2.20 below)), prevention of sludge formation, and reduction in moisture sensitivity (Borax, 2008).

Borates are also used in fireworks (to give a green colour) and as igniters for various devices including airbags (under classification C20.51.1). Borates are also used as chemical reagents (including the 'borax bead test') and plasticisers (including 'Silly Putty'), both of which would be classified under C20.59.5 (miscellaneous chemical products).

This use is discussed in more detail in Section 6.5.

### **3.2.12 Pharmaceutical preparations (C21.20)**

Borates are used in a wide range of medicaments/remedies as an antiseptic (for both consumers and in veterinary products) and to combat osteoarthritis and rheumatoid arthritis (EVM, 2003) and as an eye wash.

There is also considerable research underway into boron chemistry as an undeveloped area for new drugs<sup>14</sup>.

### **3.2.13 Glass and glass products (C23.1)**

In addition to glass fibres (see sub-section 3.2.3 above), borates are used in a range of glass and glass products where they increase the mechanical strength of glass, as well as their resistance to thermal shock, chemicals and water (IMA, 2008).

Borosilicate glass is heat-resistant glass and is associated with brand names such as Pyrex. As such, it has wide use in laboratory equipment (classification C23.19) and cookware (classification C23.13). Borates used include boric acid and disodium tetraborate (pentahydrate and anhydrous).

Borosilicate glass is also used in consumer, electronic and optical products - as discussed further below (classification C26) as well as in electrical lighting (classification C27.4).

This use is discussed in more detail in Annex 4.

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<sup>14</sup> See, for example, GlaxoSmithKline press release dated 8 October 2007 on developing new drugs based on boron chemistry (<http://www.gsk.com...>)

### **3.2.14 Refractory products (C23.2)**

Borates (such as boric oxide) are used in the manufacture of refractory bricks (C23.20.12) as used, for example, in steel smelting furnaces.

### **3.2.15 Clay building materials (C23.3) and Other porcelain and ceramic products (C23.4)**

As mentioned above (sub-section 3.2.9), one of the largest uses of borates in Europe is in frits and glazes for ceramics.

The borates serve as a fluxing agent in the glazing of a wide range of ceramic products - many of which are to be found in the home including floor/wall tiles (C23.31), housewares (C23.41) and sanitary fixtures (C23.42) (IFC, 2007). Particular use is made of boric acid (due its low sodium content). Other products include insulators (C23.43) and other technical products (C23.44).

### **3.2.16 Basic metals (C24)**

Boron is added (often in the form of boric acid) to a range of alloys (both ferrous and non-ferrous) to improve various characteristics. Relevant classifications would include ferro-alloys (C24.10.12), aluminium alloys (C24.42.2), lead, zinc and tin alloys (C24.43.2), copper alloys (C24.44.13/C24.44.2), nickel alloys (C24.45.2) and, even, uranium alloys (C24.46.1). Such alloys, in turn, are used in a wide range of products including motor vehicles (where boron-steel is used to provide additional body strength).

### **3.2.17 Nuclear reactors and parts thereof (C25.30.2)**

Nuclear reactors produce 10-15% of the energy consumed within the EU (Mantzios & Capros, 2006). Boron (in various forms) is used to control or limit the neutron flux within (and close to) many nuclear reactors. Clearly such uses would not constitute 'consumer uses'.

### **3.2.18 Computer, Electronic and Optical Products (C26)**

Borosilicate glass is used in TV and computer monitors (CRT and LCD - US EPA (2002)) as well as in a wide range of optical instruments from microscope slides to observatory mirrors. Boric oxide is often used for the manufacture of optical glass.

Such uses would be covered by C26.11.11 (cathode-ray tubes), C26.20 (computers and peripheral equipment), C26.51 (measuring, testing and navigating equipment), and C26.70 (optical instruments and photographic equipment).

### **3.2.19 Electrical Lighting Equipment (C27.4)**

Borosilicate glass is used for lights in harsh environments including automobile lights and traffic lights.



### **3.2.20 Other electrical equipment (C27.90) & Other general purpose machinery (C28.29)**

Borates are used to prevent surface oxidation during welding, brazing or soldering which could be classified as C27.90.3 if electrical and C28.29.86 if non-electrical.

### **3.2.21 Mattresses (C31.03)**

One consumer product in the home is the use of borates (boric acid) in the wadding (or cotton batting) in mattresses (and possibly other upholstered furniture) for flame and smoulder resistance. This use is discussed further in Annex 5.



## 4. IMPACT OF SECTOR-SPECIFIC LEGISLATION

### 4.1 Overview

The presence (and, in some cases, levels) of borates in some products is governed by sector-specific legislation. As such these will be excluded from consideration under the Marketing and Use Directive<sup>15</sup>. Such sector-specific legislation relevant to the borates under study includes:

- the Plant Protection Products Directive;
- the Biocidal Products Directive;
- the Cosmetics Directive;
- the Food Supplements Directive; and
- the Medicinal Products Directive.

These are considered in further detail in the sections which follow.

### 4.2 Plant Protection Products Directive

Pesticides, herbicides, etc. are governed by the Plant Protection Products Directive<sup>16</sup> (hereafter referred to as the PPP Directive). The PPP Directive is based upon a two-tier registration system, with active ingredients ('active substances') assessed at Community level for inclusion on a positive list (Annex I to the PPP Directive), and products subsequently registered by Member States. Although borates are primarily used as 'biocides' (as discussed below), they have been used more widely for plant protection.

Products containing active substances not listed in Annex 1 to the PPP Directive must be withdrawn by specified dates. As borates have not been listed in Annex I, authorisations for plant protection products containing certain borates have been progressively withdrawn as the review of active substances progresses, as summarised in Table 4.1.

<b>Table 4.1: Authorisation of Products containing Borates withdrawn under the PPP Directive</b>		
<b>Borate</b>	<b>Authorised use in products withdrawn by</b>	<b>Comment</b>
Disodium octaborate tetrahydrate (CAS 12280-03-4)	Commission Regulation (EC) No 2076/2002 of 20 November 2002	These are not included in the borates being considered for this study (see Table 1.1)
Sodium pentaborate (CAS 39326-63-1)		

<sup>15</sup> Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ L262, 27/9/1976, p201).

<sup>16</sup> Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L230, 19/8/1991, p1).

<b>Table 4.1: Authorisation of Products containing Borates withdrawn under the PPP Directive</b>		
<b>Borate</b>	<b>Authorised use in products withdrawn by</b>	<b>Comment</b>
Boric acid	Commission Decision of 30 January 2004	As first ATP entry (in Table 1.1)
Sodium tetraborate		The term 'sodium tetraborate' is most often used for disodium tetraborate decahydrate but could also cover disodium tetraborate anhydrous as well as the other hydrates (as listed in Table 1.1)

### **4.3 Biocidal Products Directive**

Biocides (not covered by the PPP Directive) are governed by the Biocidal Products Directive<sup>17</sup>. Under the Biocidal Products Directive, as for the PPP Directive, active substances are assessed at Community level for inclusion on a positive list (Annex I to the Biocidal Products Directive), and products containing them are subsequently authorised by Member States. Under the Directive, products are divided into 23 Product Types (PT, as listed in Annex V to the Directive).

Since borates in biocidal products are primarily used for timber protection/treatment (particularly as a fungicide against dry rot), the most relevant product type is PT 8 (wood preservatives).

This PT, together with rodenticides (PT 14) was on the 'first priority list'. As such, dossiers for the use of four borates (boric acid, disodium tetraborates, boric oxide and disodium octaborate tetrahydrate) in PT 8 were submitted to the relevant Rapporteur (the Netherlands)<sup>18</sup> and the Draft Evaluation Reports were subsequently published (European Commission, 2006). Due to the (then proposed) classification of borates as Reprotoxic Category 2, the Draft Evaluation Reports stated that the four borates could only be used by industrial and professional users (in accordance with Article 5(2) of the Directive<sup>19</sup>).

Other applications (and withdrawals) for borates in this and other product types are summarised in Table 4.2.

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<sup>17</sup> **Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market** (OJ L123, 24/4/1998, p1).

<sup>18</sup> Separate applications are required for each product type in which an active substance is to be used.

<sup>19</sup> Under Article 5(2) of Directive 98/8/EC, a biocidal product classified as Reprotoxic Category 2 *shall not be authorised for marketing, or use by the general public*.

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<b>Table 4.2: Borates under the Biocidal Products Directive (as of January 2008)</b>		
<b>Borate<sup>1</sup></b>	<b>Dossier submitted for</b>	<b>Notice of non-submission or withdrawal<sup>3</sup></b>
Boric acid (CAS 10043-35-3)	7 Film preservatives 8 Wood preservatives 9 Fibre, leather, rubber and polymerised materials preservatives 10 Masonry preservatives 11 Preservatives for liquid cooling and processing systems 12 Slimicides 22 Embalming and taxidermist fluids	1 Human hygiene biocidal products (November 2007) 2 Private area and public health area disinfectants and other biocidal products (November 2007) 3 Veterinary hygiene biocidal products 6 In-can preservatives (November 2007) 13 Metalworking-fluid preservatives (November 2007) 18 Insecticides, acaricides and products to control other arthropods (June 2006 and June 2007)
Disodium tetraborate - anhydrous (CAS 1330-43-4) - pentahydrate (CAS 12179-04-3) - decahydrate (CAS 1303-96-4)	7 Film preservatives 8 Wood preservatives 9 Fibre, leather, rubber and polymerised materials preservatives 10 Masonry preservatives 11 Preservatives for liquid cooling and processing systems	1 Human hygiene biocidal products (November 2007) 2 Private area and public health area disinfectants and other biocidal products (November 2007) 13 Metalworking-fluid preservatives (November 2007) 18 Insecticides, acaricides and products to control other arthropods (June 2006)
Boric oxide (CAS 1303-86-2)	8 Wood preservatives	
Disodium octaborate tetrahydrate <sup>2</sup> (CAS 12280-03-4)	7 Film preservatives 8 Wood preservatives 9 Fibre, leather, rubber and polymerised materials preservatives 10 Masonry preservatives 11 Preservatives for liquid cooling and processing systems 12 Slimicides	1 Human hygiene biocidal products (November 2007) 2 Private area and public health area disinfectants and other biocidal products (November 2007) 3 Veterinary hygiene biocidal products 6 In-can preservatives (November 2007) 13 Metalworking-fluid preservatives (November 2007) 18 Insecticides, acaricides and products to control other arthropods (June 2006)
<p>Source: DG Environment (<a href="http://ec.europa.eu/environment/biocides/index.htm">ec.europa.eu/environment/biocides/index.htm</a>)</p> <p>Notes:</p> <p>1) The more common borates are listed here. Dossiers have also been submitted for zinc borate and didecylpolyoxethylammonium borate while withdrawal notices have been issued in respect of boronphosphate glass</p> <p>2) As noted in previous table, disodium octaborate tetrahydrate is not included in the borates being considered for this study (see Table 1.1)</p> <p>3) Where a dossier (for a particular substance/PT combination) has not been submitted by the deadline, there is a three month period (from the date of the subsequent notice) during which time another party may take over the responsibility for dossier submission. If a participant does not come forward, the substance/PT combination will not be authorised (for inclusion in Annex I to the Directive).</p>		

## 4.4 Cosmetics Directive

### *The Directive and Borates*

Cosmetic products are regulated by the Cosmetics Directive<sup>20</sup>. This Directive includes lists of substances that are prohibited for use in cosmetics (Annex II) and that are subject to conditions when used in cosmetics (Annex III). Borates are listed in Annex III and may be used subject to the conditions listed in Table 4.3.

Table 4.3: Annex III Restrictions on Borates in Cosmetics				
Substance	Product	Max. Conc. (as boric acid)	Other Conditions	Warning Labels
Boric acid, borates and tetraborates	Talc	5%	Not for children <3	Not for children <3
			Not to be used on peeling/irritated skin (if conc. >1.5%)	Not to be used on peeling/irritated skin
	Products for oral hygiene	0.1%	Not for children <3	Not for children <3
				Not to be swallowed
	Other products (excluding bath & hair waving products)	3%	Not for children <3	Not for children <3
			Not to be used on peeling/irritated skin (if conc. >1.5%)	Not to be used on peeling/irritated skin
Tetraborates	Bath products	18%	Not for children <3	Not for children <3
	Hair waving products	8%		Rinse well
Source: 24 <sup>th</sup> Commission Directive 2000/6/EC of 29 February 2000 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.				

### *Restrictions on CMR Substances*

The 7<sup>th</sup> Amendment of the Cosmetics Directive<sup>21</sup> (*Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003*) introduced a range of new measures relating to the safety and testing of cosmetic products including Article 4b which states:

*The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited...*

Although derogations are possible for category 3 substances, this would not apply to borates with their proposed classification as category 2 substances.

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<sup>20</sup> Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L262, 27/9/1976, p169)

<sup>21</sup> Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending [the Cosmetics Directive] (OJ L66, 11/3/2003, p26).

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## 4.5 Food Supplements Directive

Article 4 of the Food Supplements Directive<sup>22</sup> states that only vitamins and minerals listed (in Annex I to the Directive) may be used in food supplements. However, Article 6 allows unlisted vitamins and minerals to continue to be used until 31 December 2009 provided that the European Food Safety Authority (EFSA) has not given an unfavourable opinion.

No boron compounds are among the vitamins and minerals listed in Annex I of the Directive. Following adoption of the Directive, the European Parliament requested EFSA to provide opinions on a number of vitamins and minerals - including boron.

In the resulting opinion, EFSA (2004) state that boron may have a beneficial effect on bone calcification and maintenance and derive a tolerable upper intake level (UL) of boron (in the form of boric acid or borates) of 10mg B/day for adults. Furthermore, boron intakes are likely to be less than the UL - although the consumption of boron supplements may lead to intakes which exceed the UL.

The opinion concludes with a recommendation to gather more data on boron consumption in different Member States.

## 4.6 Medicinal Products Directive

The Medicinal Products Directive<sup>23</sup> regulates *any substance or combination of substances presented for treating or preventing disease in human beings* (Article 1.2) whilst a similar Directive applied to veterinary products<sup>24</sup>.

Medicinal products are authorised and registered through a centralised procedure which is maintained by the European Medicines Agency (EMA - based in London).

The use of borates (particularly boric acid) appears to be fairly limited in authorised medicines - although examples can be found for eye treatments (humans) and in certain veterinary products. It is worth noting that it is likely that 'personal care' products containing borates will be covered by either the Cosmetics Directive (such as mouth washes) or the Medicinal Products Directive.

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<sup>22</sup> **Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements** (OJ L183, 12/7/2002, p51-57)

<sup>23</sup> **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** (OJ L311, 28/11/2001, p67) - as amended by Directive 2004/27/EC.

<sup>24</sup> **Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products** (OJ L311, 28/11/2001, p1) - as amended by Directive 2004/28/EC.

## **4.7 Uses of Further Interest**

### **4.7.1 Overview**

In order to identify the ‘*prioritised uses*’ of borates (i.e. those uses with a significant degree of exposure and which are not regulated by sector-specific legislation) which are of further interest to this study, a screening of all the uses identified in Section 3 has been undertaken. The aim of such screening is to eliminate those uses which are covered by sector-specific legislation which is more appropriate for addressing their risks (as discussed above), as well as those uses where there is unlikely to be a significant degree of risk to consumers taking into account the type and degree of exposure. This will enable a focus on the actual uses which are likely to be of concern and which are within the scope of Directive 67/548/EEC (and thereon, any possible restrictions under the Marketing and Use Directive) and of this study.

The screening is therefore provided below in three stages:

- screening by existence of sector-specific legislation;
- screening by the type and degree of exposure; and
- screening by concentration limits specified under Directive 67/548/EEC.

### **4.7.2 Screening by Existence of Sector-specific Legislation**

The uses listed in Table 3.1 were reviewed with the following questions:

- was the identified product group covered by one of the pieces of sector-specific legislation considered in the preceding sub-sections?
- was the identified product group likely to be available to and used by consumers (as opposed to just professional users)?

If the answers were ‘no’ and ‘yes’ respectively, then the product group would be taken forward to the next stage of the analysis - as summarised Table 4.4.

<b>Table 4.4: Borates in Products, Relevant Legislation and Use by Consumers</b>				
<b>Code</b>	<b>Product</b>	<b>Governed by Sector-Specific Legislation?</b>	<b>Product Available to Consumers?</b>	<b>Further Analysis?</b>
<b>B08.91</b>	<b>Chemical and fertiliser minerals</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C10.86	Homogenised food preparations and dietetic food (including food supplements)	Yes (see 4.5)	Yes	No
<b>C13.20</b>	<b>Woven textiles</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C16.21</b>	<b>Veneer sheets and wood-based panels</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C17.11</b>	<b>Pulp</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C17.21</b>	<b>Corrugated paper and paperboard and containers of paper and paperboard</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C20.13	Other inorganic basic chemicals	No	Unlikely	No
C20.20	Pesticides and other agrochemical products	Yes (see 4.2/3)	Yes	No



<b>Table 4.4: Borates in Products, Relevant Legislation and Use by Consumers</b>				
<b>Code</b>	<b>Product</b>	<b>Governed by Sector-Specific Legislation?</b>	<b>Product Available to Consumers?</b>	<b>Further Analysis?</b>
	(including plant protection products and biocides)			
<b>C20.30</b>	<b>Paints, varnishes and similar coatings, printing ink and mastics</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C20.41</b>	<b>Soap and detergents, cleaning and polishing preparations</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C20.42	Perfumes and toilet preparations (including cosmetics)	Yes (see 4.4)	Yes	No
C20.51	Explosives	No	Occasionally (fireworks?)	No
<b>C20.59</b>	<b>Other chemical products n.e.c.</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C21.20	Pharmaceutical preparations (including medicinal products)	Yes (see 4.6)	Yes	No
<b>C23.13</b>	<b>Hollow glass</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C23.14</b>	<b>Glass fibres</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C23.19</b>	<b>Other processed glass, including technical glassware</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C23.20	Refractory products	No	Unlikely	No
<b>C23.31</b>	<b>Ceramic tiles and flags</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C23.41</b>	<b>Ceramic household and ornamental articles</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C23.42</b>	<b>Ceramic sanitary fixtures</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C23.43	Ceramic insulators and insulating fittings	No	No	No
C23.44	Other technical ceramic products	No	Unlikely	No
<b>C24.10</b>	<b>Basic iron and steel and ferro-alloys</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C24.42</b>	<b>Aluminium</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C24.43</b>	<b>Lead, zinc and tin</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C24.44</b>	<b>Copper</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C24.45</b>	<b>Other non-ferrous metal</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C24.46	Processed nuclear fuel	No	No	No
C25.30	Steam generators, except central heating hot water boilers	No	No	No
<b>C26.11</b>	<b>Electronic components</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C26.20</b>	<b>Computers and peripheral equipment</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C26.51</b>	<b>Measuring, testing and navigating equipment</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C26.70</b>	<b>Optical instruments and photographic equipment</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C27.40</b>	<b>Electric lighting equipment</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C27.51</b>	<b>Electric domestic appliances</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
<b>C27.52</b>	<b>Non-electric domestic appliances</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>
C27.90	Other electrical equipment	No	Unlikely	Yes
C28.29	Other general-purpose machinery n.e.c.	No	Unlikely	Yes
<b>C31.03</b>	<b>Mattresses</b>	<b>No</b>	<b>Yes</b>	<b>Yes</b>

#### 4.7.3 Screening by Type and Degree of Exposure

Taking forward the uses identified in Table 4.4 as not being covered by sector-specific legislation, a further screening was carried out on the basis of whether the borates are present as a substance, in preparations or in an article. Where for a given use, the borates are deemed to be present only in articles, this use is not taken forward on the basis that the

degree of risk is unlikely to be significant and in any case, the use will not be covered by the possible restrictions (which would only cover the presence of borates as substances and preparations on the EU market).

The screening, however, also provides a relative comparison (or risk ranking) of the actual levels of exposure of consumers to the borates. For instance, the presence of borates in preparations such as in detergents or fertilisers is considered to lead to a much greater potential for consumers to be exposed to borates (in contrast to glass and ceramics) since the borates are 'free' constituents.

For the purposes of this analysis, such exposure (where the borates are likely to be present as 'free' constituents) has been categorised as having '*potential for significant exposure*' (Level 1) whilst that for glass products (and comparable products) (where the borates are chemically and/or physically bound) has been categorised as '*minimal potential for exposure*' (Level 3). Between these extremes, there are other products for which the exposure merits further consideration and in these cases the exposure has been categorised as having '*potential for possible exposure*' (Level 2). For these Level 2 uses, the intention is that the use of borates is done by professionals. As such, there is no direct risk to consumers from the 'formulation' stage (addition of borates). However, the resultant products may be used by consumers in such a way as to result in exposure.

Use of these categories of exposure enabled a simple screening process to be undertaken based on exposure potential as shown in Table 4.5 below. This screening process has resulted in three uses of borates which it is suggested should be considered in more detail where these have been characterised as those with *potential for significant exposure* (Level 1). Those uses with *potential for possible exposure* (Level 2) are considered in detail in Annex 5 while those with *minimal potential for exposure* (Level 3) are not considered further (except for glass, taking into account the scale of use).

<b>Table 4.5: Screening of Products by Type and Degree of Consumer Exposure</b>					
<b>Code</b>	<b>Product</b>	<b>Substance</b>	<b>Preparation</b>	<b>Article</b>	<b>Comment</b>
<b>Level 1: Potential for Significant Exposure</b>					
B08.91	Chemical and fertiliser minerals	<b>Yes</b>	<b>Yes</b>	No	Borates may be present in product as 'free' constituents with potential for significant exposure.
C20.41	Soap/detergents, cleaning and polishing preparations	Possibly	<b>Yes</b>	No	
C20.59	Other chemical products n.e.c.	Unlikely	<b>Yes</b>	No	Borates may be present as an ingredient in preparations such as lubricants and brake fluids where there may be potential for significant exposure
<b>Level 2: Potential for Possible Exposure</b>					
C16.21	Veneer sheets and wood-based panels	Unlikely	Unlikely	<b>Yes</b>	Although exposure is likely to be minimal, these products may be worthy of further investigation.
C17.21	Corrugated paper and paperboard (incl. containers)	Unlikely	Unlikely	<b>Yes</b>	
C31.03	Mattresses	Unlikely	Unlikely	<b>Yes</b>	

<b>Table 4.5: Screening of Products by Type and Degree of Consumer Exposure</b>					
<b>Code</b>	<b>Product</b>	<b>Substance</b>	<b>Preparation</b>	<b>Article</b>	<b>Comment</b>
C20.30	Paints, varnishes and similar coatings, printing ink and mastics	Possibly	<b>Yes</b>	No	Frits & glazes used in ceramics are very unlikely to result in exposure to borates for consumers (although their application by professionals might).
<b>Level 3: Minimal Potential for Exposure</b>					
C13.20	Woven textiles	No	No	<b>Yes</b>	Borates are chemically/physically bound into fibre glass and glass products - which makes it very unlikely for consumers to be exposed to borates.
C23.13	Hollow glass	No	Uncertain	<b>Yes</b>	
C23.14	Glass fibres	No	Uncertain	<b>Yes</b>	
C23.19	Other processed glass, including technical glassware	No	Uncertain	<b>Yes</b>	Borates are chemically/physically bound into ceramic products - which makes it very unlikely for consumers to be exposed to borates.
C23.31	Ceramic tiles and flags	No	No	<b>Yes</b>	
C23.41	Ceramic household and ornamental articles	No	No	<b>Yes</b>	
C23.42	Ceramic sanitary fixtures	No	No	<b>Yes</b>	Borates are chemically/physically bound into alloys - which makes it very unlikely for consumers to be exposed to borates.
C24.10	Basic iron and steel and ferro-alloys	No	No	<b>Yes</b>	
C24.42	Aluminium	No	No	<b>Yes</b>	
C24.43	Lead, zinc and tin	No	No	<b>Yes</b>	
C24.44	Copper	No	No	<b>Yes</b>	
C24.45	Other non-ferrous metal	No	No	<b>Yes</b>	As outlined in Section 3.2.17, borosilicate-glass may be found in a range of electrical and measuring equipment but, as above, the presence of such glass is very unlikely to result in exposure to borates.
C26.11	Electronic components	No	No	<b>Yes</b>	
C26.20	Computers and peripheral equipment	No	No	<b>Yes</b>	
C26.51	Measuring, testing and navigating equipment	No	No	<b>Yes</b>	
C26.70	Optical instruments and photographic equipment	No	No	<b>Yes</b>	As for ceramics, the use of borates in enamels on appliances very unlikely to result in exposure to borates.
C27.40	Electric lighting equipment	No	No	<b>Yes</b>	
C27.51	Electric domestic appliances	No	No	<b>Yes</b>	
C27.52	Non-electric domestic appliances	No	No	<b>Yes</b>	

#### **4.7.4 Screening by Concentration Limits**

##### ***Prescribed Limits for Borates under 30<sup>th</sup> and 31<sup>st</sup> ATPs***

The five entries for borates in the 30<sup>th</sup> ATP contain a range of concentration limits from 3.1% (diboron trioxide) to 8.5% (borax decahydrate). Taking account of the presence of boron in each of these entries reveals that the each of the concentration limits are based on a limit of 1% boron - as illustrated in the example below:

<i>Limit for borax pentahydrate:</i>	<i>6.5% (see Table at end of Annex 1)</i>
<i>Molecular weight (MW):</i>	<i>291.4 (see Entry 8, Annex 2)</i>
<i>Contribution to MW from boron:</i>	<i>43.2 (= 4 boron atoms with atomic weight 10.8)</i>
<i>Equivalent limit for boron:</i>	<i><math>6.5\% \times 43.2/291.2 = 0.96\%</math></i>

For the first entry on the yet-to-be adopted 31<sup>st</sup> ATP for dibutyltin hydrogen borate, no concentration limits are prescribed. Accordingly, the ‘default’ limit<sup>25</sup> is 0.5%. However, as already noted in Table 1.1, this compound has already been banned in concentrations of greater than 0.1% (Directive 89/677/EEC).

For the other two entries on the yet-to-be adopted 31<sup>st</sup> ATP relating to sodium perborate, using the basic formulae for the monohydrate and tetrahydrate gives a boron equivalent of 0.7% in each case. Whether this is intentionally different from the borates under the 30<sup>th</sup> ATP or is intended to account for other possible molecular structures is not known.

### ***Implications***

Preparation will not be subject to the R60-61 classification where the boron equivalent concentration is much less than around 1%. Such preparations, therefore, will not be affected by possible restrictions nor be prohibited from consumer use.

### ***Review of Products against Concentration Limits***

Each of the products listed in Table 4.5 with *potential for significant exposure* (Level 1) was reviewed with particular regard to the likely presence of borates (and equivalent boron concentration). The results are summarised in Table 4.6.

<b>Table 4.6: Presence of Borates in Products under Further Investigation</b>			
<b>Code</b>	<b>Product</b>	<b>Likely Presence of Borates</b>	<b>Retained for Further Analysis</b>
B08.91	Chemical and fertiliser minerals	As discussed in Section 6, boron containing fertilisers contain 2-14% boron	Yes
C20.41	Soap and detergents, cleaning and polishing preparations	There are two main uses of borates in detergents: 1) sodium perborate as a bleaching agent in detergents at typical concentrations of 10-15% (>1% boron); and 2) boric acid (and disodium tetraborate decahydrate) as an enzyme stabiliser in liquid detergents at concentrations much lower than 1% boron	1) Yes  2) No
C20.59	Other chemical products n.e.c.	Depending on the product, could be significant boron concentrations present	Yes

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<sup>25</sup> As set out in Table VI of **Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions to the classification, packaging and labelling of dangerous preparations** (OJ L200, 30/07/1999, p1).

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## 5. ASSESSMENT OF DEGREE OF EXPOSURE AND RISKS

### 5.1 Restrictions on CMRs

Within the EU, there are action plans to improve public health. In response to these action plans, restrictions on the marketing and use of certain dangerous substances and preparations have been introduced.

More specifically, an action plan to combat cancer from 1996<sup>26</sup> was one of the drivers for the 25<sup>th</sup> Amendment to the Marketing and Use Directive in 2003<sup>27</sup> which listed a number of substances classified as carcinogenic, mutagenic or toxic to reproduction (CMRs) of category 1 or 2. In accordance with Directive 94/60/EC<sup>28</sup>, such CMRs and preparations containing them *should not be placed on the market for use by the general public* (taking account of the associated risks and benefits).

Similarly, a subsequent action plan adopted in 2002<sup>29</sup> was one of the drivers for the 29<sup>th</sup> Amendment to the Marketing and Use Directive in 2006<sup>30</sup> which listed a further number of substances classified as carcinogenic, mutagenic or toxic to reproduction (CMRs) of category 1 or 2. Such CMRs and preparations containing them *should be subject to restriction for sale to the general public* (taking account of the risks and advantages of the newly-classified substances, as well as of the Community legislative provisions on risk analysis).

Although the wording in the 29<sup>th</sup> Amendment appears slightly less forceful than that in the 25<sup>th</sup> Amendment, there is a clear message that CMRs (Category 1 or 2) should not be

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<sup>26</sup> Decision No 646/96/EC of the European Parliament and of the Council of 29 March 1996 adopting an action plan to combat cancer within the framework for action in the field of public health (1996-2000) (OJ L95, 16/04/1996, p9).

<sup>27</sup> Directive 2003/36/EC of the European Parliament and of the Council of 26 May 2003 amending, for the 25th time, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classified as carcinogens, mutagens or substances toxic to reproduction — c/m/r) (OJ L156, 25/06/2003, p26).

<sup>28</sup> Directive 94/60/EC of the European Parliament and of the Council of 20 December 1994 amending for the 14th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ L365, 31/12/1994, p1).

<sup>29</sup> Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (OJ L271, 09/10/2002, p1).

<sup>30</sup> Directive 2005/90/EC of the European Parliament and of the Council of 18 January 2006 amending, for the 29th time, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classified as carcinogens, mutagens or substances toxic to reproduction — c/m/r) (OJ L33, 04/02/2006, p28).

present as substances or in preparations and sold to the general public (subject to consideration of the associated risks and benefits).

In the previous section, consideration was given to a wide range of uses of borates. Given the diversity of products containing borates, it is likely that nearly all EU consumers will be exposed to products containing borates. However, the degree of exposure to borates will vary greatly from one product to another.

In relation to the individual consumer, the level of risk associated with the presence of borates in products, with particular reference to those preparations/mixtures containing borates (at concentrations above the limits in the 30<sup>th</sup> and proposed 31<sup>st</sup> ATP), will depend on two key factors:

- the frequency of use of preparations/mixtures containing borates; and
- the degree of exposure to borates associated with particular preparations/mixtures.

The analysis presented in the previous section resulted in the identification of several ‘*prioritised uses*’ of borates for which consumers would be expected to have the ‘*potential for significant exposure*’. In each case, borates would be present in preparations at sufficient concentrations that the preparations themselves would be labelled as R61 or R60-61 (i.e. toxic to reproduction category 2).

In such cases, it would be expected that, more or less by definition, the risks to human health (associated with the ‘*potential for significant exposure*’) would be significant and, as such, restrictions on the sale of such preparations to the general public would be expected (on risk grounds at least).

## **5.2 Risks and Borates**

There have been various authoritative studies on the developmental toxicity risks associated with the ingestion of borates. Some of the more prominent studies are summarised in Table 5.1.

<b>Table 5.1: Summary of Limit Values for Developmental Toxicity</b>		
<b>Reference</b>	<b>Limit Value</b>	<b>Comment</b>
HERA (2002)	NOAEL: 7 mgB/kg/day	Derived for sodium perborate
EVM (2003)	‘Safe upper limit’: 0.16 mgB/kg/day	Derived by dividing NOAEL (9.6 mgB/kg/day) by uncertainty factor of 60
Umweltbundesamt (2007)	NOAEL: 7 mgB/kg/day	Derived for sodium perborate as presented in the draft RAR in 2003 and re-presented in the final RAR in 2007
US EPA (2004)	Reference Dose: 0.2 mgB/kg/day	Derived by dividing ‘benchmark dose’ (10.3 mgB/kg/day) by uncertainty factor of 66 (and rounding)
EFSA (2004)	‘Tolerable upper intake level’ (UL) 0.16 mgB/kg/day	Derived by dividing NOAEL (9.6 mgB/kg/day) by uncertainty factor of 60

Table 5.1 illustrates a considerable degree of consensus. In summary, the NOAEL value is of the order of 10 mgB/kg/day, which when combined with an uncertainty factor of 60 gives a 'safe' limit value of the order 0.16 mgB/kg/day or, more simply, 10 mgB/day (for an adult). For simplicity, the (daily) tolerable upper intake level (UL) values recommended by EFSA will be used when considering the degree of risk associated with exposure to borates.

### 5.3 Exposure in Fertilisers

While it is expected that most fertilisers would be sold to professional farmers, in some geographic regions, farmers constitute a significant portion of the local population<sup>31</sup> and can therefore, qualify as the 'general public'. Almost anyone can be farmer - as it essentially involves an ownership interest in crops or livestock - and the purchase of fertilisers is generally open to both professional farmers and the general public<sup>32</sup>.

For those farmers (and other consumers such as gardeners) applying boron fertilisers, there will be the possibility of some transfer of material from hand to mouth. The amount of material (such as soil) ingested has been subject of many studies with particular regard to children. The amount of material inadvertently ingested is typically reported to be of the order of 50-100 mg/day (where this excludes deliberate ingestion - known as Pica behaviour).

However, for construction workers the US EPA has historically used values as high as 480 mg/day although in a detailed critique (ACC, 2006) this value has been rebutted as being excessive.

For the purposes of this analysis, it has been assumed that inadvertent ingestion of boron fertilisers (amongst those farmers using such fertilisers) is unlikely to exceed 100 mg/day. Since boron fertilisers may contain around 10% boron, it would appear that the intake of boron could approach the tolerable upper intake level (UL) value of 10 mgB/day (as recommended by EFSA). However, the UL value is based on consideration of routine daily exposures whereas fertilisers would only be applied sporadically during the course of a year.

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<sup>31</sup> By way of example, about a third of Romanian employment is in agriculture (Eurostat (2008): **Agricultural Statistics**).

<sup>32</sup> It is acknowledged that there is an EU proposal to restrict the sales of ammonium nitrate fertilisers to the general public: **Proposal for a Decision of the European Parliament and of the Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylene diphenyl diisocyanate, cyclohexane and ammonium nitrate**, COM(2007) 559 final, 2.10.2007

On this basis, it is considered unlikely that the exposure to boron through the use of boron fertilisers would routinely exceed the UL value of 10 mgB/day. This, in turn, suggests that, although borates are likely to be present as free constituents in boron fertilisers and are classified as toxic to reproduction category 2, the associated risks to farmers (and other consumers) using boron fertilisers are unlikely to be of serious concern.

## **5.4 Exposure in Detergents**

Consumer exposure to borates (with particular reference to sodium perborate tetrahydrate) is examined in detail in the EU Risk Assessment Report (Umweltbundesamt, 2007).

The results are summarised in Table 5.2.

<b>Table 5.2: Summary of Consumer Exposure to Borates in Detergents</b>		
<b>Scenario</b>	<b>External Dose (via dermal exposure)</b>	<b>Frequency of Exposure</b>
Handling of heavy duty detergents	13.2 mg PBS per exposure i.e. 0.9 mgB per exposure	Up to 5 times per week
Hand-washing with heavy duty detergents	61.4 mg PBS per exposure i.e. 4.3 mgB per exposure	Up to 6 times per week
Handling of machine dish-washing detergents	7.6 mg PBS per exposure i.e. 0.5 mgB per exposure	7 times per week
<i>Note: PBS is acronym used for sodium perborate tetrahydrate in the RAR</i>		
<i>Source: Table 4.11 of RAR (Umweltbundesamt, 2007)</i>		

With regard to the values presented in Table 5.2, it should be noted that where the frequency of exposure is near daily, the daily dose will be similar to the dose per exposure.

On this basis, it can be seen that consumers who frequently use detergents for hand-washing may be exposed to average daily doses of about 4 mgB/day. In the EU Risk Assessment Report (RAR), the associated uptake is assumed to be 1% of the external dose. As such, the average daily uptake will be about 0.04 mgB/day, which is well below the various limit values listed in Table 5.1 and the RAR concluded that such exposures were ‘negligible’.

## **5.5 Exposure in Other Chemical Products**

As discussed in more detail in Section 6.5, it is acknowledged that borates are used in a wide range of preparations which may be covered by the product classification C20.59 - *Other chemical products n.e.c.* Such products include: antifreezes (for engine coolant), brake fluids, lubricants, metalworking fluids, water treatment chemicals and fuel additives.



Although some of these products (such as water treatment chemicals) are likely to be primarily for professional use, others may be intended for both professional and consumer use. However, the key point to note is that these products will only be handled by consumers on an occasional basis. In other words, they will not be used by consumers on a daily or even a weekly basis. As such, the low frequency of use of these products will, in turn, result in very low levels of exposure. By comparison with the cases for fertilisers and detergents presented above, it can be reasonably concluded that the mean daily uptake will be much lower than the daily tolerable upper intake level of 10 mgB/day.

On this basis, it is concluded that the associated risks will be negligible.

## 5.6 Exposure in Glass/Ceramics

Typical compositions of borosilicate glass and general purpose E-glass fibres are summarised in Table 5.1.

<b>Table 5.3: Constituents of Borosilicate Glass and E-Glass Fibres</b>							
<b>Glass</b>	<b>SiO<sub>2</sub></b>	<b>B<sub>2</sub>O<sub>3</sub></b>	<b>CaO</b>	<b>Al<sub>2</sub>O<sub>3</sub></b>	<b>Na<sub>2</sub>O/ K<sub>2</sub>O</b>	<b>Other Oxides</b>	<b>Fluorine</b>
B-S Glass	70-80%	7-13%	<1%	<2%	4-16%		
E-Glass Fibres	50-60%	5-10%	20%	10-15%	<1%	<4%	<1%
<i>Sources: Various including Wallenberger et al (2001), <a href="http://glassproperties.com">glassproperties.com</a> and <a href="http://www.britglass.org.uk">www.britglass.org.uk</a></i>							

The production of glass results in a crystal lattice of inter-connected oxide molecules. During production, boron converts to a form a vitreous glass network of three or four co-ordinated boroxol rings when melted. The properties of borate glass can be explained by boron changing from the three-fold triangular co-ordination to the four-fold tetrahedral co-ordination. This would increase the connectivity of the network, resulting in an increase in glass transition temperature and a decrease in thermal expansion coefficient (Eurima, 2007).

As a consequence, the presence of borates in glass products is extremely unlikely to result in any significant exposure of borates to consumers using such products (since the borates are chemically bound into the product).

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<sup>33</sup>. 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

<sup>33</sup> Sources include: [www.borax.com](http://www.borax.com) and [universalborates.com/industries/ceramics.html](http://universalborates.com/industries/ceramics.html)

study) will be zero - since they have been chemically transformed in the glass/glaze/enamel/ceramic production process<sup>34</sup>. 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.

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<sup>34</sup> This approach is reflected in the recent REACH Regulation in which glass and ceramic frits are deemed to be 'substances' in their own right (**Commission Regulation (EC) No. 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V**, OJ L268, 09/10/08, pp14-19).

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## 6. POTENTIAL SOCIO-ECONOMIC IMPACTS OF RESTRICTIONS

### 6.1 Introduction

This Section aims to investigate the potential for restrictions and/or use of alternatives for the ‘*prioritised uses*’ (taking into account any relevant EU-wide and/or national legislation).

In assessing the potential socio-economic impacts (costs and benefits) of any restrictions on the sale of specified borate-containing products to consumers, it is important to identify the potential actors who may be affected. Based on the information obtained from consultation, the supply chain for borates appears to flow from the:

Manufacturers/Importers<sup>35</sup> of borates à  
Suppliers of borates à  
Producers of borate-containing products<sup>36</sup> (downstream users of borates) à  
Distributors<sup>37</sup> à  
End users (including consumers).

The impacts of any potential restrictions on the manufacturers/importers and suppliers of borates are, therefore, considered first in this Section. The prioritised uses are then considered further as follows:

- use in/as a fertiliser mineral (Section 6.3);
- use in soaps, detergents, cleaning and polishing preparations (Section 6.4); and
- use in other chemical products (Section 6.5).

For each prioritised use, the discussion below provides (based on the information made available from consultation and a literature review):

- a background to the use of borates in a given sector;
- a description of the market for borates in the identified sector (supply chain, quantities used, trends, etc);

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<sup>35</sup> According to the REACH Regulation, *manufacturer* means any natural or legal person established within the Community who manufactures a substance within the Community. *Importer* means any natural or legal person established within the Community who is responsible for import (i.e. the physical introduction into the customs territory of the Community). A *supplier* of a substance or a preparation means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation.

<sup>36</sup> According to the REACH Regulation, a *producer* of an article means any natural or legal person who makes or assembles an article within the Community. *Downstream user* means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.

<sup>37</sup> *Distributor* means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

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- the types of borates used and the concentrations of borates in the end-products (and a further consideration of the potential risk vis-à-vis existing legislation);
- a consideration of the criticality of borates to the end-product or sector and the potential for substitution or use of alternatives; and
- a cost-benefit analysis of the potential impacts of restrictions.

As set out in the Project Specification, priority has been given to those uses for which any potential restrictions would be expected to have the greatest impact. Further information on other uses of borates is provided in Annexes 4 (use in glass) and 5 (other uses).

## **6.2 Impacts on Manufacturers/Importers and Suppliers of Borates**

### **6.2.1 Market Profile**

#### ***Supply Chain***

As noted in Section 2, borates are not mined (significantly) within the EU-27 and the vast majority of borates consumed must be imported into the EU as raw or refined materials or in the form of finished products. Most imports are from Turkey and the USA and the top five importers in the EU are Belgium, Germany, Netherlands, Spain and France.

The European Borates Association (EBA) represents the major manufacturers, importers and suppliers of borates in the EU, in particular, Rio Tinto Minerals (USA), Eti Mine Works (Turkey) and Societa Chimica Larderello (Italy) (EBA, 2008a). As discussed in Section 2, the borate mining industry in Turkey accounts for around 45% of world production of boron mineral and is dominated by Eti Mine Works while the US borate industry accounts for around 20% and is dominated by Rio Tinto Borax. While these three companies would clearly account for a significant proportion of the borates supplied into the EU and appear to show vertical integration across their supply chain (i.e. involvement and control of manufacture, import and supply of borates to downstream users), their exact market share is unknown. There are indeed other companies who have similar arrangements for borates coming into the EU from Chile and Peru (which account for 8.5% and 0.2% of world production of boron mineral respectively), for instance.

In terms of imports, it appears to be the case that the major importers/suppliers supply borates to specific geographic regions of Europe; for instance, one importer/supplier could have exclusive supply of the borates mined by a given company to northern Europe, while another supplier would be responsible for southern Europe (or specific countries therein) (EBA, 2008). As noted in Section 2, the countries with the largest imports would be expected to have either processing facilities and/or to be a 'gateway' for imports to neighbouring countries (as is the case for the Netherlands).

The distribution network could, however, vary. One company indicates that it sells its products through more than 10 importers/ distributors across the EU with each distributor having an assigned territory where it actively sells to SME end-users and small retailers.

In addition to territorial distribution, the distributors in some cases are specialized in certain markets (i.e. fertiliser). Another company has 400-500 direct customers operating in around 750 locations - with each customer receiving borates in bulk by truck, rail or barge, depending upon location, quantity and type of borate in question. It also has around 20 distributors located in around 90 locations across Europe who in turn stock the materials and supply to end-users (EBA, 2008).

Overall, EBA (2008a) believes that its members have around 95% of the market share for the main borates: boric acid, boric oxide, borax anhydrous, borax pentahydrate and borax decahydrate. It is, however, noted that other borates are indeed used in significant quantities and these may be controlled by other non-EBA member companies.

### *Types of Borates Supplied and Trends in Use*

Table 6.1 below sets out the tonnages of borates manufactures and supplied to various industry sectors in the EU in 2007 while Table 6.2 following provides the trends in tonnages over the last five years - based on information provided by (seven) EBA members that responded to the questionnaire for this study.

<b>Table 6.1: Types of Borates Produced and Supplied in the EU (2007)</b>			
<b>Name</b>	<b>CAS No.</b>	<b>Volumes (t/y)</b>	
		<b>Production</b>	<b>Supply</b>
Boric Acid	10043-35-3	13,000	169,000
Boric Oxide (or Diboron Trioxide)	1303-86-2	0	1,300
Disodium Tetraborate, Anhydrous (Boric Acid, Disodium Salt)	1330-43-4	100	26,000
Disodium Tetraborate Decahydrate (Borax Decahydrate)	1303-96-4	3,000	27,000
Disodium Tetraborate Pentahydrate (Borax Pentahydrate)	12179-04-3	12,000	352,000
<b>Total</b>		<b>28,100</b>	<b>~573,300</b>
<i>Source: EBA (2008)</i>			
<i>Note that there are other types of borates which are produced or supplied in the EU, but these are in much lesser quantities overall - and are outside the scope of the study.</i>			

Table 6.2: Sources of Borates in the EU (Production, Import and Supply)				
Year	Production volume (tonnes)	Import volume (tonnes)	Supply volume (tonnes)	*Production location / Source of Import
2007	28,000	527,000	576,000**	USA / Turkey / France / Spain / Italy / Chile / Peru
2006	27,000	490,000	537,000	
2005	27,000	500,000	544,000	
2004	30,000	528,000	562,000	
2003	31,000	499,000	524,000	
Source: EBA (2008)				
* Most borates are imported into Europe; however, some are refined or modified further in Europe before being supplied to customers				
** The difference in tonnages supplied to the EU in 2007 (576,000 in this Table and 573,300 in Table 6.1) is probably due to rounding errors				

Based on the above tables, it can be assumed - for the purposes of this study - that around 600,000 tonnes of borates are supplied to the EU per annum (where around 95% of the market share is equivalent to ~570,000 tonnes). This estimate is reasonably consistent with the estimates presented in Table 2.2 which show that around 615,000 tonnes of borates are imported into the EU-27 with imports from Turkey and USA alone accounting for around 80% of all imports.

EBA estimates that around 80% of the above borates end up in consumer products, 5% in professional products and 15% in industrial products and applications. These are, however, purely estimates as there is substantial crossover between products used by consumers and industrial users and, in many cases, borates end up in industrial products which are ultimately used by consumers (EBA, 2008). As already discussed (see Section 5.6), in most of the products used by consumers, the borate is not released because it has been chemically reacted with other chemicals to form a new substance.

### ***Trends in Use***

Although Table 6.2 suggests a reasonably stable situation; in practice, there has been a reduced demand for sodium perborate (used as bleach in detergents) counterbalanced by an increased demand in most application areas, particularly in agriculture and vitreous (or selected high temperature) applications (such as insulation fibre glass (IFG), borosilicate glass and frits & ceramics) (EBA, 2008).

Over the next five years, demand for borates is forecast to increase by 2%-4% per annum. The reasons for this are increasing demands for insulating products (IFG) which contribute towards climate change policy goals and the general upgrading of housing stock throughout the EU, which positively impacts the demand for ceramic frits and glazes. Additionally, the borosilicate glass sector is expanding with substantial increases in pharmaceutical glass demand forecast in addition to tubing for the heat collection elements in solar panels and e-glass (automobile & infrastructure). Demand is also forecast to grow modestly in a number of other end-uses such as timber preservation, metallurgy, flame retardance, and cleaning; while in agriculture, growth similar to that in the vitreous sectors is anticipated (EBA, 2008).

At the national level, no difference in trends is expected; although it is possible that demand for borate containing products are possibly higher in Eastern Europe in line with the high level of construction activity in that region.

## **6.2.2 Impact of Potential Restrictions**

Table 6.3 below provides an overview of the main products, applications or industry sectors in which borates are used. As can be seen from the Table, the major use of borates in the EU is in glass and glass products (including ceramics) although this is not being considered as a prioritised use within the context of this study.

<b>Table 6.3: Volume of Borates Supplied to Various Products, Applications or Industry Sectors</b>		
<b>Products, Applications or Industry Sectors</b>	<b>Total Volume of Borates Supplied</b>	
	<b>%</b>	<b>Tonnes</b>
Glass and glass products and ceramics	55.8%	334,800
Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	16.8%	100,800
Fertilisers and nitrogen compounds	4.7%	28,200
Chemical and fertiliser minerals	2.4%	14,400
Paper and paper products (including corrugated paper)	1.5%	9,000
Basic pharmaceutical products and preparations	1.4%	8,400
Wood products (e.g. veneer sheets and wood-based panels) - except furniture	1.0%	6,000
Paints, varnishes, coatings, printing ink and mastics	0.5%	3,000
Furniture (e.g. mattresses)	0.1%	600
<b>Other chemicals and chemical products:</b> Various chemical processes including metallurgy, antifreeze, brake fluids, buffers, wallboard, lubricants	8.2%	49,200
<b>Others:</b> Steel slag stabilisation, flame retardance, cellulose insulation, nuclear, electroplating	7.6%	45,600
<b>Total</b>	<b>100%</b>	<b>600,000</b>
<i>Source: EBA (2008)</i>		

Assuming that restrictions are placed on the marketing of borates to consumers, EBA (2008) estimates that the total cost to all their members would be in the region of €140 million - relating to a loss of sales or revenue. Although the precise derivation is not known, since EBA estimates their annual turnover at €175 million<sup>38</sup>, the potential restrictions would be expected to reduce their annual turnover by around 80%<sup>39</sup>.

The consequent effects of this, combined with reduced demand and regulatory complexity at the customer levels, would be that some manufacturing plants and depots may be forced to close. Employment will be affected in most sectors of the business with numbers of employees decreasing in production to depot packing operations, although there may be an increase in administrative resources required to ensure compliance with the regulations. EBA also believes that there is a reasonable possibility that prices will weaken, leading to lower profitability (although this is currently unclear) and a reduction in research and development activities, with further subsequent impacts on profitability (EBA, 2008).

<sup>38</sup> Interestingly, dividing €175 million by the total tonnage supplied (576,000 tonnes) indicates a value of about €300 per tonne (i.e. €0.3 per kg) which is the value derived from the import/export data presented in Section 2.2.

<sup>39</sup> This is very much a 'worst-worst' case and assumes that restrictions would impact the major markets including the use of borates in glass (and ceramics). Since glass is not a preparation/mixture, the use of borates in glass would not trigger a restriction under Directive 94/60/EC (see Section 5.1).

Based on the analysis in the previous sections, it is highly unlikely that restrictions will be placed on uses accounting for up to 80% of current tonnages. Three scenarios would appear to be more realistic:

- as a *worst case* scenario, restrictions could result in the loss of market in uses accounting for 45% of current tonnages (i.e. all uses of borates except in glass and glass products and ceramics will be affected);
- as a *medium case* scenario, restrictions could result in the loss of market in uses accounting for 25% of current tonnages in total (i.e. uses in soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations and in fertiliser minerals will be affected in the main); and
- as a *best case*, restrictions could result in the loss of market in uses accounting for 10% of current tonnages in total.

Applying an average sale price of €300 per tonne of borates<sup>40</sup> to the tonnages of borates lost under the various scenarios gives total costs of around €18 million (best case), €45 million (medium case) and €81 million (worst case) per annum (see Table 6.4 below).

As highlighted by EBA, due to the dynamic nature of the borates industry (with suppliers constantly winning and losing business), it is difficult to predict precisely what the impact would be on individual companies (EBA, 2008).

To provide an indication of the incidence of the resulting impacts, and using the total value of lost sales and revenue of **€18 million to €45 million per annum**<sup>41</sup>, it is assumed that:

- borates production accounts for costs of up to 50% of the total sales value, equivalent to between €9 million and €22.5 million. As borates are not mined (significantly) within the EU-27, the majority of this loss in sales will be incurred by non-EU companies;
- importers and suppliers will incur the remaining 50% loss in revenue, equivalent to between €9 million and €22.5 million, where this is assumed to cover operational costs and any 'mark-up'. It is assumed here that this is incurred entirely by EU companies who are primarily the importers and suppliers of these borates; and
- the actual profit margin (after removal of operational costs, etc.) can be assumed to be around 10%, equivalent to between **€900,000 and €2.5 million per annum** with this then reflecting the actual economic loss to the EU borates industry (as shown in Table

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<sup>40</sup> This is consistent with the information in Section 2 which shows that the value of exports is around €320 per tonne (€0.32 per kg) and that for imports is around €270 per tonne (€0.27 per kg).

<sup>41</sup> The worst case loss of revenue is not taken forward in the study as it is clearly unrealistic (on the basis of the number of uses considered prioritised uses) in the context of this study.

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6.4). It is worth noting that most of the importers/suppliers of borates (who responded via EBA) are SMEs who may be impacted more heavily than larger companies.

<b>Table 6.4: Cost of Potential Restrictions for Manufacturers, Importers and Suppliers of Borates</b>			
	<b>Worst Case</b>	<b>Medium Case</b>	<b>Best Case</b>
Quantity of borates supplied to the EU (tonnes) (2007)	600,000	600,000	600,000
% of supply volume affected by potential restrictions	45%	25%	10%
Equivalent tonnage of borates affected by potential restrictions	270,000	150,000	60,000
Cost of boron (€/tonne)	€300	€300	€300
Total lost sales or revenue	€81 million	<b>€45 million</b>	<b>€18 million</b>
Loss of revenue for EU importers/suppliers (50%)	€40.5 million	<b>€22.5 million</b>	<b>€9 million</b>
Actual profit lost by importers/suppliers (10%)	€4.5 million	<b>€2.5 million</b>	<b>€900,000</b>

In terms of wider impacts, according to the EBA, impacts on overall competitiveness cannot be stated with certainty; however, it is likely that any restrictions on some end-uses of borates would reduce choice and hence competitiveness. New investments will be predominantly made outside the EU where the use of borates will still be authorised. However in some applications, particularly in the vitreous sector, the elimination of borates would limit options. In many cases, it may not be technically feasible to offer some products if borates are excluded (EBA, 2008).

## 6.3 Use in Fertiliser Minerals

### 6.3.1 Background to Use of Borates

Boron is one of the seven elements<sup>42</sup> which are essential to plant growth and classified as ‘micro-nutrients’. As such, boron containing fertilisers are applied to a diverse range of crops and plants (both commercially and by consumers).

### 6.3.2 Market Profile and Consultation Findings

Information was received from two importers/suppliers of borates for use in the fertiliser industry located in Belgium (*Company A*) and the Netherlands (*Company B*) and from two downstream users of borates for production of fertilisers located in the UK (*Company C*) and Belgium (*Company D*).

*Company A* imports and supplies around 1,000 tonnes of boric acid per annum mainly from Chile; 90% of this tonnage is supplied to the fertiliser industry while 10% is supplied to the glass industry. They do not, however, consider themselves to account for a

<sup>42</sup> The seven elements are boron, chlorine, copper, iron, manganese, molybdenum and zinc.

significant market share of the EU market in either sector. On the other hand, *Company B* supplies only around 50 tonnes of boric acid per annum to the fertiliser industry; they, however, consider themselves to account for a significant market share in the EU for boron containing chelated micronutrient mixes. Both companies indicate that the trend across the EU in the last five years has shown a slight increase in demand with the main suppliers to the EU being Turkey, USA, Russia and Chile. *Company B*, however, expects a strong increase if agriculture develops into a soil-less culture. Many crops need around 25 micromol/l Boron constantly in the water they receive and this need has to be covered.

With regard to the downstream users of borates for production of fertilisers, *Company C* (which holds 10 – 20% of the boron ethanolamine micronutrient fertiliser market) purchases around 1,000 tonnes of borates per annum; this volume has been stable in the last five years, although there is an anticipated growth related to increase in oilseed rape (OSR) production for biodiesel (for which boron is a critical nutrient). *Company D* purchases around 3,000 tonnes of borates (specifically: boric acid, borax decahydrate and borax pentahydrate) per annum; this volume has increased almost 75% in the last five years and they indicate that the demand of borate for fertilisation is growing due to the EU agricultural policy revision, and the increasing demand for bio-fuels (boron is used for sugar beet and colza). Over 90% of the end-products containing these borates are sold within the EU. Overall, the supply chain for this sector appears to flow from:

Miner/Producer of boric acid à  
Importer/Supplier (*Companies A & B*) à  
Producer of fertilisers/micronutrient mixes (*Companies C & D*) à  
Distributors à  
End users (includes consumers and framers).

One of the downstream user companies indicated that they obtained their supplies of borates directly from two manufacturers (or alternatively a retailer) while the other purchases from traders (sourcing from South America, Russia and Turkey). Each company could have any number of distributors (one company indicates it has more than 100) and the end-users could include industrial, professional and consumer users (of which there could be thousands).

### **6.3.3 Concentrations and Types of Borates Used**

The Fertilisers Regulation<sup>43</sup> sets out detailed technical provisions regarding the scope, declaration, identification and packaging of four main types of fertiliser:

- main inorganic nutrient fertilisers (nitrogen, phosphorus and potassium);
- secondary inorganic nutrient fertilisers (calcium, magnesium, sodium and sulphur);
- inorganic micro-nutrient fertilisers (boron, cobalt, copper and iron); and
- ammonium nitrate fertilisers of high nitrogen content.

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<sup>43</sup> **Regulation (EC) No. 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers**, (OJ L304, 21/11/2003, p1).

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The inorganic micro-nutrient fertilisers contain elements required in small quantities for plant growth, of which boron is one of them. Any fertiliser which complies with this regulation is designated an 'EC fertiliser' on the basis that:

- under normal conditions of use it does not adversely affect human, animal, or plant health, and the environment;
- it provides nutrients in an effective manner; and
- appropriate sampling, analysis, and if required, test methods are available.

The Fertilisers Regulations allow the use of boric acid, sodium borates, calcium borates, boron ethanolamine and borated fertilisers either in solution or in suspension with minimum boron content between 2-14% (w/w) expressed as boron (as shown in Table 6.5 below) and these fertilisers are subject to its provisions. Zinc borate and disodium octaborate tetrahydrate also appear to be used, although in smaller quantities (based on information provided through consultation).

<b>Table 6.5: Minimum Content of Nutrients for Boron-containing Fertilisers</b>			
<b>No</b>	<b>Type designation</b>	<b>Method of Production and Essential Ingredients</b>	<b>Minimum Content of Nutrients (% by weight)</b>
1a	Boric acid	Product obtained by the action of an acid on a borate	14 % water-soluble B
1b	Sodium borate	Chemically obtained product containing as its essential component a sodium borate	10 % water-soluble B
1c	Calcium borate	Product obtained from colemanite or pandermite containing as its essential ingredient calcium borates	7 % total B
1d	Boron ethanol amine	Product obtained by reacting a boric acid with an ethanol amine	8 % water-soluble B
1e	Borated fertiliser in solution	Product obtained by dissolving types 1a and/or 1b and/or 1d	2 % water-soluble B
1f	Borated fertiliser in suspension	Product obtained by suspending types 1a and/or 1b and/or 1d in water	2 % water-soluble B

One of the responding companies indicated that while they will try to reduce the boron levels in their fertilisers to below the threshold level indicated in Annex 1 of the 30<sup>th</sup> ATP (equivalent to around 1% boron in a micronutrient mix) to avoid classification (since they cannot handle a classified product in their factory), they highlight that the agronomical plant need figures are higher (often around 1.5% boron in micronutrient mixes).

Taking into account that boron is essential for plant life and many forms of agriculture will not be possible without it, they expect that farmers will add separate boron products to their fertiliser mixes. Hence, the threshold values may have little or no impact on any risk faced by the farmer.

#### **6.3.4 Criticality of Borates**

Boron is considered critical to many crops including oilseed rape and sugar beet which are particularly prone to boron deficiency with resultant poor yield and/or disease. In sugar beet, boron deficiency results in black rot in the middle of the sugar beet (*phoma betae*) and loss of root yield, sugar and technologic quality; while in colza, boron deficiency results in loss of flowering and fertility.

Other critical crops are fruit, vegetables and forestry (an emerging area for boron, with the development of biomass use). It is also indicated that foliar fertilisation is mandatory in cases of water deficiency. Overall, the agricultural sector requires boron as a micronutrient, as specifically acknowledged in the Fertilisers Regulation. This is not to suggest that the application of boron is required in all locations for all crops but rather there may be a requirement for certain crops in specific areas of boron deficiency.

#### **6.3.5 Potential Substitution of Borates**

By definition, there are no alternatives to boron when a crop is boron-deficient. Furthermore, the associated risks to farmers (and other consumers) using boron fertilisers are unlikely to be of serious concern (as discussed in Section 5.3). This accords with Article 14(c) of the Fertilisers Regulation, in that a boron-containing fertiliser *does not adversely affect human, animal, or plant health, or the environment* (under normal conditions of use). With these points in mind, a detailed assessment of alternatives is not required.

However, as noted earlier, although boric acid, sodium borate, calcium borate, boron ethanolamine and zinc borate may be used as boron fertilisers, only boric acid and sodium borate are currently covered by the proposed classification of borates.

#### **6.3.6 Impact of Potential Restrictions**

With regard to the impacts on importers or suppliers of borates, *Company A* estimates that the cost of any potential restriction will be around €700 million from loss of sales or revenue. It is not clear how this figure has been derived. *Company B* has not calculated the cost to the company from potential restrictions (and the consequent substitution) of borates; however, they note that the loss of revenue or sales may not be as significant since borates are a small part of their overall portfolio.

Both companies expect a moderate decrease in supply tonnages (with changes to manufacturing processes); however *Company B* notes that a decrease in micronutrient mixtures could be partly compensated by selling single metal chelates without the boric acid, which then have to be mixed in on the next level in the market or by the farmer (or end-user). Both companies expect an increase in the market price of borates and boron-containing mixes. *Company B* expects costs relating to new recipes for mixes, higher blending costs and costs for precautions at the feed end of the equipment. Both companies also expect research and development activities to decrease as it would no

longer make sense to develop micronutrient mixes if you cannot go up to the level of the plants need for boron.

With regard to the downstream users of borates, *Company C* indicates that if boric acid is banned in the EU, this would prevent their manufacture of boron ethanolamine. They estimate their annual sales of boron ethanolamine at around €1.5 million per annum. This is similar to the cost estimate provided by *Company D* of between €1 million and €2 million (in recurring costs) due to loss of sales or revenue.

In terms of total costs of any potential restrictions across the industry, it is currently unclear how many companies are actually involved in the use of borates in the manufacture of inorganic micro-nutrient fertilisers in the EU. As an indicator, a review of company websites suggests around 10 companies. However, based on Table 6.3, it appears that about 40,000 tonnes of borates are used in fertilisers<sup>44</sup>. The information provided by the responding companies accounts for around 5,000 tonnes of borates (assuming no double-counting) - about 12% of the total tonnage. This seems to be consistent with the estimated 10 companies taking into account that none of the responding companies appears to account for a significant market share of the EU market in this sector.

Assuming that all downstream users of borates are unable to sell their products, using the cost of €1,500 per tonne of product (as indicated by *Company C*) indicates a possible loss of revenue of €60 million. Assuming a lower cost of €300 per tonne of product indicates a possible loss of revenue of between €12 million.

Wider impacts of a potential restriction may, however, be expected. For instance, if the potential restriction affected the production of a specific product (e.g. boron containing chelated micronutrient mixes), substance (boron ethanolamine) or crop (e.g. OSR for biofuels). Impacts on farmers and lost produce cannot be quantified without knowing for sure the extent to which yields are affected (for instance, if producers simply dilute their products and farmers buy more quantities). If significant, negative impacts on food production may be expected. In terms of overall competitiveness, some companies indicated that they expect that small producers and suppliers will be affected and there may be some employment effects (for instance, higher controls and training of employees may be required).

## **6.4 Soap and Detergents, Cleaning and Polishing Preparations**

### **6.4.1 Background to Use of Borates**

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<sup>44</sup> This, of course, is a tiny fraction of the 20 million tonnes of fertilisers containing nitrogen, potassium and phosphorous applied in the EU each year (based on statistics from the European Fertilizer Manufacturers Association ([www.efma.org](http://www.efma.org)))

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Boric acid and disodium tetraborate decahydrate are used as enzyme stabilisers in liquid fabric detergents, as well as in a range of cosmetics and oral hygiene products.

Borax pentahydrate is the borate used to produce sodium perborate which is used as an oxidizing and bleaching agent in detergent products (and other cleaning products) (CEFIC, 2008).

#### 6.4.2 Market Profile and Consultation Findings

Information for this study was received from:

- the European Association for soaps, detergents and maintenance products (AISE) and a national association (UKCPI);
- one EU importer of borates (as well as producer of perborates) for use in the manufacture of soaps and detergents;
- two downstream users of borates in the manufacture of washing powders and similar products; and
- the CEFIC peroxygens/perborate sector group which represents sodium perborate manufacturers<sup>45</sup>.

CEFIC (2008) indicates the manufacture in 2007 of around 196,000 tonnes of perborates which are used in soaps and detergents. This is equivalent to an input of around 90,000 tonnes of borax pentahydrate. This latter figure is consistent with the estimate of 100,800 tonnes provided in Table 6.3 for the detergents/cleaning sector with the remainder being used in other products (e.g. cleaning and polishing preparations, perfumes and toilet preparations, etc). By way of example, one company which manufactures such products indicated that they use around 7,200 tonnes of boric acid and sodium tetraborate in enzyme stabilisation for their products (which include disinfectants).

Table 6.6 sets out the market situation in terms of production, sales and export of sodium perborates over the last ten years.

<b>Table 6.6: Production, Sales and Export of Sodium Perborate (1997 - 2007)</b>					
<b>Year</b>	<b>Production (tonnes/year)</b>	<b>Sales in Europe (tonnes/year)</b>	<b>Sales in Europe (%)</b>	<b>Exports (tonnes/year)</b>	<b>Exports (%)*</b>
1997	569,900	421,600	74%	153,000	27%
2003	318,750	188,000	59%	130,750	41%
2004	294,000	N/A		N/A	
2005	199,000	N/A		N/A	
2006	178,000	N/A		N/A	
2007	196,000	54,000	28%	142,000	72%
<i>Source: CEFIC (2008) and Umweltbundesamt (2007) for 1997 data</i>					
<i>* Exports as percentage of European production</i>					
<i>Production locations: Austria, Slovenia, Spain and Germany.</i>					

As can be seen, production of sodium perborates has decreased significantly over the last ten years. A more drastic reduction can be seen in the amount of sales made within

<sup>45</sup> Note that borates are the raw materials for the production of sodium perborate - hence, sodium perborate manufacturers are thus downstream users of boric acid/borates.

Europe, with intra-EU sales dropping from 74% in 1997 to 28% in 2007. CEFIC (2008) estimates that if sales to only Western Europe are considered (i.e. removing the Central and East European tonnages), the sales actually decreased from 134,000 tonnes in 2003 to 24,850 tonnes in 2007, making intra-EU sales account for only around 18% of all production. CEFIC believes that the uncertainty relating to the proposed classification and labelling and the availability of a replacement chemical (percarbonate) are the main reasons for this decline (CEFIC, 2008). They note that very little sodium perborate is imported (as has been the case since 1997 when only 1% of the total production quantity was imported (Umweltbundesamt, 2007) and that the existing four producers (with an estimated annual turnover of around €90 million) control close to 100% of the market.

One of the producers/importers of borates indicates that for their company, the quantity of borates imported and perborates manufactured has been constant in the last few years. The company expects a similar trend in the future, since they export most of the perborates to markets outside the EU, where consumption of perborates in the detergent industry is increasing and there are no suitable substitutes for perborate (in these regions).

This company obtains its borates from two suppliers who obtain directly from the main miners/producers of borates. While the production of perborates is carried out wholly within the EU, sales are directed mostly towards regions and markets outside EU.

Overall, the supply chain for this sector appears to flow from (CEFIC, 2008):

Miner/Producer of borates →  
Importer/Supplier (of borax pentahydrate raw material) →  
Manufacturers of Perborate →  
Detergent industry (direct or via distributors) →  
Retailers → consumer (general public).

### **6.4.3 Concentrations and Types of Borates Used**

Based on the information collected from consultation and literature review, the main borates used in the soaps, detergents and cleaning products industry are:

- boric acid (CAS No. 10043-35-3);
- disodium tetraborate, anhydrous (CAS No. 1330-43-4);
- disodium tetraborate, decahydrate (CAS No. 1303-96-4); and
- perboric acid, sodium salt (CAS No. 11138-47-9) - which is essentially a mixture of the monohydrate (CAS No. 10332-33-9) and the tetrahydrate (CAS No. 10486-00-7).

AISE considers boric acid and sodium perborate to be of particular importance in the detergents sector. For:

- **Boric acid:** AISE notes that boric acid is typically used (as an enzyme stabiliser) in detergents at levels below the specific concentration limit for reproductive toxicity (i.e. below 5.5% - other consultees indicated typical borate concentrations from 1% to



2.5%). Although this means that the use of boric acid would not be affected by potential restrictions on uses of borates as substances or in preparations (above specific concentration limits laid down in the annex of the ATP) by consumers, the presence of such borates in a product will nevertheless be communicated via websites (in compliance with the Detergent Regulation). Industry has expressed the view that this may result in undue concern to consumers who use (and may have done so for many years) detergent products that contain this substance; and

- **Sodium perborate:** AISE notes that the EU Risk Assessment of sodium perborate concluded that the use of perborate in detergents is safe for consumer uses (as outlined in Section 5.4). The proposed hazard-based classification for sodium perborate will apply above the specific concentration limits of 6.5% and 10% for the monohydrate and for the tetrahydrate respectively. So companies using sodium perborate above the specific concentration limits will either have to reformulate their products to stay below these levels or look for substitutes.

#### **6.4.4 Criticality of Borates**

The use of boric acid to stabilize enzymes in liquid detergents may be considered critical to the sector. According to AISE (2008), enzymes are indispensable for sustainable formulations of detergents as they allow effective stain removal at low temperatures, thereby saving energy and water. In order to undertake any substitution, reformulation would have to be undertaken and stability studies done.

#### **6.4.5 Substitution of Borates**

Based on information received from companies and the literature review, sodium percarbonate is a commercially available substitute for sodium perborates in detergents. It shows technical suitability in many applications comparable to sodium perborate; although it is indicated to lack robustness in some special applications (e.g. dental care).

It is, however, the case that some detergent manufacturers have deliberately chosen not to change their production formula containing sodium perborate, either in order to minimize the risks inherent to changing formula or because they also sell detergents in countries having a particularly hot and humid climate (CEC, 2006). In hot regions of Europe, Asia and Africa (which constitute a major market for detergent manufacturers), sodium percarbonates have limited use because their stability in such conditions is indicated to be inferior to that of sodium perborates.

Other issues identified by the companies include:

- percarbonates have to be stored in dry and sun protected areas and, as such, there would be a need to rebuild the raw material storage places for some companies;
- percarbonates are very reactive and may cause explosion/fire in case of uncontrolled contact with water and raw materials that accelerate decomposition (like organic

compounds or metal ions). On the other hand, the borates do not require special attention during handling and production; and

- usage of percarbonates in washing powders formulations require carton packaging (boxes) with high water protection; it will therefore, significantly increase cost of packaging.

#### **6.4.6 Cost of Restriction**

The impacts of potential restrictions on the use of sodium perborate in soaps and detergents would vary across the supply chain. Table 6.7 provides a qualitative overview of the likely impacts.

<b>Table 6.7: Possible Impacts of Restrictions on Actors in Supply Chain for Sodium Perborates</b>	
<b>Actor in Supply Chain</b>	<b>Likely Impact of Potential Restrictions</b>
Miner/producers of borates	There may be some loss of production of borates (see Section 6.2); however, the extent of this loss is uncertain. However, no wider impacts should be expected for manufacturers and suppliers of hydrogen peroxide. <sup>46</sup>
Importer/supplier (of raw material))	There may be some loss incurred by importers and suppliers (see Section 6.2); however, the extent of this loss is uncertain.
Manufacturers of perborate	<p>The impact should be minimal on the basis that since 2002 (at the earliest), a number of industry market projections expected the switch from sodium perborates to sodium percarbonates to be completed by 2005. Note that in 2002, sodium perborate was thought to account for around 45% of all persalts production, while sodium percarbonate accounted for 55% (CEC, 2006).</p> <p>While the costs of this switch-over are significant (as described in Table 6.8), it is the case that since 2002 at the earliest, at least four plants in Spain, Italy, Germany and Sweden have either built new capacity or converted part of their existing plants to be able to manufacture up to 180,000 tonnes of sodium percarbonate. Any costs relating to the switch-over from sodium perborates to sodium percarbonates would, therefore, be better considered as business or investment costs, relating to a change in the market (as opposed to a change brought about by the potential restrictions currently being considered).</p> <p>It is recognised that sodium perborates are still being produced to meet demand by detergent manufacturers; however, losses in this area (due to potential restrictions) would be compensated by an equivalent demand for sodium percarbonates. Note that (based on data for up to 2006) around 75-80% of sodium percarbonates/ perborates are purchased by the four large soaps and detergents companies (CEC, 2006). This is unlikely to change.</p>
Detergent manufacturers	With regard to EU sales, the impacts are likely to be minimal as around 80% of detergents currently manufactured are based on sodium percarbonate.

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<sup>46</sup> Sodium perborate is manufactured from a chemical reaction between hydrogen peroxide, caustic soda (or sodium hydroxide) and borates (such as sodium borate). Sodium percarbonate is manufactured from a chemical reaction between hydrogen peroxide and soda ash (or sodium carbonate).

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<b>Table 6.7: Possible Impacts of Restrictions on Actors in Supply Chain for Sodium Perborates</b>	
<b>Actor in Supply Chain</b>	<b>Likely Impact of Potential Restrictions</b>
Detergent manufacturers (continued)	<p>EU exports of detergents are a major market and may account for 50-70% of production capacity and annual turnover for the EU companies. Although it is possible that the new borate classification may impact on the use of perborates in detergents destined for export from the EU, any reduction in the use of perborates would expect to be counteracted by an increased use of percarbonates.</p> <p>Although AISE (representing detergent manufacturers) regrets the borates reclassification decision, they do not intend to request any exception to the possible restriction at this stage. They, however, forwarded the questionnaire to their member companies and national associations - so that individual companies that may wish to apply for an exception to the possible restriction (e.g. if they use borates in different applications than those covered by the risk assessments or use other substances than those discussed above) can respond directly. The UK Cleaning Products Industry Association sent a response indicating that they fully support the position communicated by AISE (UKCPI, 2008).</p>
Retailers	Impacts of restrictions should be minimal (especially in Western Europe) where over 80% of detergents in the shops are based on sodium percarbonate.
Consumers	Impacts of restrictions should be minimal (especially in Western Europe) where over 80% of detergents in the shops are based on sodium percarbonate.

<b>Table 6.8: Summary of Responses by Companies to Consultation</b>
<p>Information provided by CEFIC (2008) indicates that the existing four producers of sodium perborates have an estimated annual turnover of around €90 million. They estimate a possible loss of around €50 million per year in annual turnover in the event of any restrictions (<i>although this 'loss' would simply be replaced by an equivalent gain in sales of sodium percarbonate</i>). Various other costs indicated by companies include those relating to:</p> <ul style="list-style-type: none"> <li>• a likely shutdown of sodium perborate production (<i>although as discussed in Table 6.1, this has been foreseen for several years</i>);</li> <li>• a large amount or surplus of raw materials (e.g. hydrogen peroxide) which cannot be used/sold (<i>it is currently unclear why such raw materials, in particular, hydrogen peroxide would not be used as it is essential for sodium percarbonate manufacture</i>);</li> <li>• modification of existing equipment (as these cannot be used for manufacture of an alternative product) and changes to manufacturing processes. One company estimates the costs of dismantling their installations and reshuffling to a competitive product at around €40 million. Another company estimates that such modification would cost approximately €10 million; however, if required to set up new production (of an alternative product), the cost would be approximately €30 million;</li> <li>• personnel lay-offs due to a restructuring of R&amp;D activity. One company predicts loss of employment for approximately 60 people;</li> <li>• termination of long lasting contracts;</li> <li>• rebuilding of warehouses to deal with percarbonates which require sun and moisture protection. Also, line modification to avoid percarbonates dust contact with other materials that may cause decomposition in dust storage;</li> <li>• developing and testing new formulations and new packaging material (as well as implementation). Percarbonates are indicated to be around 30% more expensive than perborates; and</li> <li>• some (as yet unpredictable) impact on the price of borates due to the disappearance of detergent industries. Some impacts on overall competitiveness may also be expected but these are not stated.</li> </ul>

## 6.5 Other Chemicals and Chemical Products

### 6.5.1 Background to Use of Borates

Borates are widely used in the manufacture of a number of other chemicals and chemical products. Some of the applications (Borax, 2008) include uses in:

- **antifreezes (for engine coolant):** where the buffering action of borates keeps the pH above seven preventing acid formation and inhibiting corrosion (corrosive organic acids are produced by the oxidation of glycol-based anti-freezes);
- **brake fluids:** where borates act to prevent ‘vapour lock’ due to water absorption by the system which reduces the boiling point (and effectiveness) of the brake fluid;
- **lubricants:** where borates form an extremely resilient film on metal load-bearing surfaces, in addition to their corrosion protection and pH buffering properties;
- **metalworking fluids:** where borates act as bacteriostatic agents and corrosion inhibitors. Boric acid esters have led to high quality water-miscible cutting fluids with longer emulsion charge life;
- **water treatment chemicals:** where borates promote the formation of a passivating layer or film which prevents further oxidation or corrosion of metals (e.g. in central heating systems, cooling towers and circulating water systems); and
- **fuel additives:** where borates have been used as gasoline additives to prevent pre-ignition, and help to keep carburettors clean.

The above uses mainly relate to industrial products and applications and would, in theory, not be directly affected by any potential restrictions on consumer use. However, some products (which contain borates as substances and preparations) are indeed placed on the market for use by the general public and, as such, would be covered by any potential restrictions. It has also been suggested that the possibility of restrictions could result in the demand for the removal of borates from those products intended for professional use.

The frequency of use of such products by consumers (as opposed to professional users) would only be occasional. With this in mind (and taking account of the likely degree of exposure), it can be reasonably concluded (as discussed in Section 5.5) that the mean daily uptake will be much lower than the daily tolerable upper intake level and, on this basis, the associated risks will be negligible.

Table 6.3 suggests that around 50,000 tonnes of borates are used in these applications. Further discussion, including information received from the questionnaires, on these uses of borates is provided below.

## **6.5.2 Market Profile and Consultation Findings**

Information on the use of borates in lubricants and metalworking fluids was received from three downstream users of borates, as well as, a submission by the Independent Union of the European Lubricants Industry (UEIL), which represents over 500 companies involved in the manufacture of lubricants across the EU. UEIL represents around 60-70% of the metalworking fluids market in Europe and a significant proportion of these use borates. As an industry, they are both users of borates and their preparations, as well as producers and users of products that contain borate preparations (UEIL, 2008).

According to UEIL, around 8,000 to 10,000 tonnes of borates are purchased and used annually in the manufacture of around 200,000 tonnes of metalworking fluid sold in Europe. In the last five years, the market has been generally static with no significant changes (UEIL, 2008).

In terms of the supply chain, the borates (primarily boric acid) are sourced primarily from the major global borate suppliers. UEIL member companies include both additive manufacturers who use borates in producing ingredients for metalworking fluid formulators, and metalworking fluid manufacturers themselves. Some fluid manufacturers also purchase borates directly for use within their own manufacturing processes. Further downstream, the supply chain can be complex. The metalworking fluids are ultimately sold to industrial end users. This is sometimes directly, particularly if the end-users are large manufacturers, or it can be through a series of sales agents, distributors and traders. Some manufacturers only sell to other businesses and not directly to the end user market (UEIL, 2008).

Of the downstream users companies that provided information on their use of borates:

- *Company M* purchases and uses around 150 tonnes of borax decahydrate (CAS No. 1303-96-4) and borax pentahydrate (CAS No. 12179-04-3) in the manufacture of lubricants for dry drawing. Around 230 kilotonnes of steel cord and bead wire is manufactured using these borates for the tyre industry exclusively. The sodium borate and sodium tetraborate are contained in dry drawing soap (12.5% by weight);
- *Company N* purchases around 700 tonnes per annum of borax pentahydrate (CAS No. 12179-04-3) and around 10 tonnes of boric acid which it uses in the manufacture of industrial lubricants. According to this company, it accounts for over 50% of the EU market for metal wire drawing soaps;
- *Company O* purchases around 200 - 250 tonnes per annum of boric acid which it uses in the production of lubricants and cutting fluids. According to this company, it accounts for over 4% of the EU market for cutting fluids and all of their end-uses are in industrial products and applications; and
- *Company P* purchases around 400 tonnes of boric acid for use in water treatment products for swimming pools. Over the last five years, the quantities purchased appear to have tripled and the company estimates that 80% of their products end up in

products used by consumers and the remaining 20% in professional products and applications. The company estimates they have around 500,000 end-users and have around 25% of the EU market share for their products.

### **6.5.3 Concentrations and Types of Borates Used**

According to UEIL (2008), the most important borate by far is boric acid (10043-35-3), with other sodium borate salts having minor importance and used in small volumes, e.g. borax pentahydrate (12179-04-3) and decahydrate (1303-96-4).

*Company O* notes that the concentration of borates in their products is between 2% and 10%. Industrial products and applications are thought to account for over 99% of the end-users and, as such, UEIL would not expect any exposure of the general public (although they expect to be affected by the potential restrictions). Within the industry, exposure to borates is primarily through skin contact, not oral administration, and this has always been regarded as low risk. Furthermore, the borates are often reacted to produce other substances that are not proposed for classification (UEIL, 2008).

For use of borates in water treatment products, *Company P* indicates that borates act as an inert additive to reduce the oxidising properties of the products and as a lubricant for the pressing of tablets. The borates account for around 8% of total weight of the product.

### **6.5.4 Criticality of Borates**

The primary functions of the borate substances in metalworking fluids are corrosion protection and pH buffering. Borate compounds offer excellent long term stability with low foam and good tolerance to hard water conditions. Yao et al (2006) also note that borate esters possess friction reducing, anti-wear and anti-oxidant characteristics in lubricating oils. According to Borax (2008), borate polyols and polyamines in lubricants form an extremely resilient film on metal load-bearing surfaces which improves load capacity and protects from wear and tear. Potassium borates are also used in high pressure lubricants due to their stable dispersion of microspheres.

Information provided by downstream user companies indicates that borates-based end products cannot be replaced in the lubricant industry with the same level of performance and cost efficiency. While a number of possible substitutes have been evaluated, at this stage, none have the same efficiency as borates and none are as cost effective. Furthermore, it is considered that the end-products are used in highly automated industries and are not in direct contact with operators. Potential restrictions on the use of borates would, overall, represent a major setback for the industry and could result in loss of business.

### **6.5.5 Potential Substitution of Borates**

According to UEIL (2008), there are no simple (drop-in) alternatives to boric acid in metalworking fluids that can be used as a direct replacement. In general, products have to be reformulated with other ingredients and the physico-chemical, functional and stability

properties assessed and maintained. One complicating feature is that the products are sold to end-users as concentrates, but are diluted with water before use. The resulting emulsions typically contain 3-20% of the concentrates. The performance, appearance and stability of the emulsions are all affected by these formulation changes and need to be assessed and optimised in addition to maintaining the characteristics of the concentrates.

This is consistent with the answers provided by the downstream users companies. *Company M* indicates that since 2003, they have been working on finding suitable substitution products for these lubricants with no success to date. *Company O* also indicates that there is no drop-in substitute for borates; only a reformulation with different materials is possible. Such reformulation will lead to a price increase of 10 - 15% on their products. They estimate one-off costs of reformulation at €100,000 and recurring costs of around €300,000.

Overall, the industry has always regarded borates to be low risk in terms of their impacts on human health (workers) and the environment. UEIL is wary that alternative formulations are unlikely to reduce any perceived risks and it is possible that in some cases, revised formulations might have greater hazards to human health and the environment, notwithstanding the proposed classification of certain borates (UEIL, 2008).

For use in water treatment chemicals, *Company P* notes that sodium sulphate may be used as an inert additive and magnesium or calcium stearate (or an external puffing system) would be used as a lubricant for pressing the tablets. These are 10 - 20% more expensive than the borates currently being used and new equipment would be required at a cost of around €200,000.

<b>Table 6.9: Summary of Availability of Alternatives to Borates in Other Chemical Products</b>		
<b>Application/Product</b>	<b>Availability of Alternatives</b>	<b>Other Comment</b>
Antifreezes (engine coolant)	Unknown	
Brake fluids	Unknown	May be a critical use
Lubricants/Metalworking fluids	No	Reformulation costs could be significant
Water treatment chemicals	Yes	Cost may need to be considered
Fuel additives	Unknown	

### **6.5.6 Impact of Potential Restrictions**

In assessing the impacts of potential restrictions, a key area of uncertainty relates to the extent to which potential restrictions on the marketing of borates as substances or in preparations (above specific concentration limits laid down in the annex of the ATP) to the general public would affect the use in industrial fluids (since, these products are generally intended for professional and industrial use). UEIL also believes that potential restrictions on the use of borates by consumers could result in the demand for their removal from products for industrial use (UEIL, 2008). According to UEIL (2008), two extreme situations are possible (with the actual impact being somewhere in between).

Restrictions on the use of borates in consumer uses could result in:

- ***Complete removal of borates:*** It has been estimated that the cost of changing to borate-free formulations adds around 30 - 50% to the formulation cost. Assuming a cost of €2,000 per reformulation in management and laboratory time, and the number of formulations containing boric acid is around 2,000, the total cost of reformulation might be estimated at around €4 million (as a one-off cost). Recurring costs in the form of increased costs of reformulated products could be around €200 million. Existing manufacturing equipment should be capable of dealing with the modified formulations and costs in this area might be expected to be minimal (UEIL, 2008).

*Company M* notes that restrictions would mean the end of their production activities as the maximum acceptable increase on cost would be around 20% (based on the same consumption for 1 tonne steel produced); and

- ***No removal of borates:*** In theory, this should mean that the formulation costs will remain unchanged. However, restriction on borates by consumers may destabilise the price of borates, and increases in formulation costs might be expected, even without changing the composition of the products. For those companies that continue to handle boric acid, they will need to invest in significant changes to their handling and manufacturing procedures as would be required with the new classification. The cost of such changes is not known, but is estimated to be €50 million - relating to plant changes. Recurring costs in the form of increased raw material prices are expected to be around €20 million.

Overall, the impact is difficult to predict, but they expect administrative costs regardless of whether products are reformulated or not as they would field a lot of queries from customers and other downstream users. UEIL stresses that a significant proportion of their members are SME organisations and consider borates to be very important to their business. They are regarded as being highly effective, low risk and difficult to replace and within many metalworking fluids, the borates are reacted to form compounds that are not proposed for classification in the 30th ATP.

For *Company P* (an SME), they estimate total costs of around €800,000; where new equipments costs are around €200,000; new tests, registration and certification of products cost another €300,000 and annual costs of €300,000. The use in tablets for swimming pools is, however, covered under the Biocides Directive.





## 7. CONCLUSIONS

### 7.1 Impacts on Prioritised Uses of Borates

#### 7.1.1 Use as Fertiliser Mineral

Boron is one of seven elements which are essential to plant growth and classified as 'micro-nutrients'. Boron containing fertilisers are applied to a diverse range of crops and plants (both commercially and by consumers) including fruit, vegetables and forestry (an emerging area for boron, with the development of biomass use). It is also considered critical to many crops (in boron-deficient regions), in particular, oilseed rape (used in the food industry and increasingly for biodiesel production) and sugar beet which are particularly prone to boron deficiency with resultant poor yield and/or disease. By definition, there are no alternatives to boron when a crop is boron-deficient.

Although the occasional application of boron fertilisers will result in exposure to borates, the level of exposure will be well below the recommended tolerable upper intake level (UL) of 10 mg boron per day. As such, the associated risks to farmers (and other consumers) using boron fertilisers are unlikely to be of serious concern.

Restrictions on the presence of borates in fertilisers placed on the market (for sale to the general public) could result in three possible impacts:

- ***a switch to other borate compounds:*** Of the five boron compounds which may be used as boron fertilisers (as identified in the Fertilisers Regulation), only boric acid and sodium borate are currently covered by the recent classification of borates. Manufacturers of boron-containing fertilisers may, therefore, switch to other borates with minimal socio-economic impacts. However, the risks associated with these 'alternatives' would effectively be the same (as the risks are associated with the presence of boron);
- ***an increase in quantities purchased by farmers and consumers:*** Manufacturers of boron-containing fertilisers may reduce the concentrations of borates to below the limits in Annex I of Directive 67/548/EEC. To counter this, farmers would simply add larger quantities of boron fertilisers to their crops, potentially increasing their costs (although this may be absorbed in reduced prices of the 'diluted' product); and
- ***loss of market:*** It is estimated that around 42,000 tonnes of borates are currently used in fertilisers. Due to inherent uncertainties in the response of manufacturers and consumers (as well as the extent to which yields may be affected), the exact impact of any potential restrictions cannot be predicted with certainty at this point. However, assuming that downstream users of borates are unable to sell their products to the end-users (or farmers) as a result of the classification, the possible loss of revenue could be in the region of €12 to €60 million with the possibility of wider impacts on specific products and/or lost produce/reduced yield.

Overall, there is a real possibility that any potential restrictions on the use of borates as a fertiliser mineral would result in costs to the industry and consumers with minimal (or no) benefit in terms of risk avoided. In any event, the risks associated with boron fertilisers are unlikely to be of serious concern.

### **7.1.2 Use in Soaps and Detergents**

Boric acid and disodium tetraborate decahydrate are used as enzyme stabilisers in liquid fabric detergents, as well as in a range of cosmetics and oral hygiene products. Sodium perborate (manufactured from boric acid) is used as an oxidizing and bleaching agent in detergent products (and other cleaning products - with possible overlaps with the Biocidal Products Directive).

The use of borates is considered critical in its use to stabilize enzymes in liquid detergents and it is claimed that no suitable alternatives are currently known. However, the concentrations used are below the limits in Annex I of the Directive 67/548/EEC and would, therefore, not be covered by any potential restrictions.

More generally, it is estimated that around 100,000 tonnes of these borates are used in soaps and detergents, as well as in other cleaning products. Over the last five years, the use of sodium perborate in detergent products marketed across Western Europe has decreased by around 80% and sodium perborates have been largely replaced by sodium percarbonates.

Although detergents using sodium perborate would be classified as preparations which are toxic to reproduction (as a result of the 30<sup>th</sup> and 31<sup>st</sup> ATPs), the EU Risk Assessment Report on sodium perborate concludes that consumer exposures to sodium perborate (and, hence, the risks) in detergents are 'negligible'. On this basis, an exception to the standard restriction may be applicable to detergents as there are no unacceptable risks.

In relation to the impact of potential restrictions, the sodium perborate manufacturers indicate that sodium percarbonate delivers a similar technical performance to perborates when used in colder climates. In other words, there are tried and tested alternatives to sodium perborate (for colder climates). However, EU exports of detergents are a major market and may account for 50-70% of production capacity and annual turnover for the EU companies. Although it is possible that the proposed perborate classification (under the yet-to-be adopted 31<sup>st</sup> ATP) may impact on the use of perborates in detergents destined for export from the EU, any reduction in the use of perborates would expect to be counteracted by an increased use of percarbonates. This assumes that suitable technological developments are found to overcome some of the difficulties of handling sodium percarbonate in warmer climates).

Overall, it is considered that any costs relating to the switch-over from sodium perborates to sodium percarbonates would be better considered as business or investment costs relating to a change in the market (since some EU companies have already invested significantly in such changes) - as opposed to a change brought about by the potential restrictions currently being considered. Also, it is the case that any potential restrictions

would be targeted at products currently placed on the EU market (with exports being outside the scope of any restrictions). As such, the impacts of any restrictions would, therefore, depend on the strategic business response of individual manufacturers (which cannot be predicted at present).

### **7.1.3 Use in Other Chemical Products**

Borates are widely used in industrial fluids such as antifreezes, lubricants, brake fluids, metalworking fluids, water treatment chemicals and fuel additives. The functions of the borates in these fluids include: corrosion inhibition, buffering action, lubrication, stabilisation of thermal oxidation; etc.

These uses mainly relate to industrial products and applications and would, in theory, not be directly affected by any potential restrictions on consumer use. However, some products (which contain borates as substances and preparations) are indeed placed on the market for use by the general public and, as such, would be covered by any potential restrictions. It has also been suggested that the possibility of restrictions could result in the demand for the removal of borates from those products intended for professional use. The total cost of reformulation for use in lubricants and metal-working fluids alone is estimated (by industry) at around €4 million (as a one-off cost) with recurring costs of around €200 million.

Even if no removal of borates is required from these products, it is indicated that the potential restrictions may destabilise the price of borates, and increases in formulation costs might be expected (even with no change in product composition). For those companies that continue to handle boric acid, they will need to invest in significant changes to their handling and manufacturing procedures as would be required with the new classification. The cost of such changes is not known, but the lubricants industry estimates these to be around €50 million (relating to plant changes) with recurring costs in the form of increased raw material prices expected to be around €20 million.

Since the associated risks to consumers (i.e. non-professional users) are considered to be negligible, it is unlikely that these costs of potential restrictions would be outweighed by the benefits to such consumers.

## **7.2 Impacts on Other Uses of Borates**

### **7.2.1 Use of Borates in Adhesives, Paper and Pressed Panels**

For uses in:

- **starch adhesives:** taking the example of a toddler chewing pieces of cardboard containing starch adhesive, the resultant exposure will be well below the tolerable upper intake level of 3 mg B/day recommended by EFSA for toddlers (aged 1-3);

- **cellulose insulation:** as this product is usually applied by professionals and even the keenest DIY (do-it-yourself) person is unlikely to be insulating their house every few years, the associated exposure will be very limited (when considered over a period of years); and
- **veneer sheets and pressed panels:** although consumers would not be involved with the fabrication of veneer sheet and pressed panels, they could be used by consumers in DIY projects. Some exposure could be associated with dust generated when such items are sawn into the desired shape. However, as for the insulation case above, it is very unlikely that this would result in regular or routine exposure.

It is estimated that, in total, around 15,000 tonnes of borates are used in adhesive, paper and pressed panel applications; around 9,000 tonnes are used in paper and paper products and around 6,000 in wood products (veneer sheets and pressed panels). The impacts of potential restrictions on these uses cannot be predicted with certainty at present; however, the analysis indicates that the risk avoided would be negligible.

### **7.2.2 Use in Paints and Coatings**

In paints and coatings, borates are multi-functional coating additives with flame retardant, corrosion inhibiting and buffering properties which may be found in offset printing inks and interior wall paint.

While it is estimated that around 3,000 tonnes of borates are used annually in this sector, it is noted that the majority of respondents use other borates not listed in the ATPs and the thresholds mentioned in the ATPs mean that many products will not be affected (due to the low concentrations of borates used). In addition, these products are intended for professional and industrial uses that are covered by the relevant worker safety legislation. In some applications, it is currently unclear whether borates can be substituted (e.g. in intumescent coatings, where they serve a critical life-saving function).

Overall, based on the information provided, the impacts of the potential restrictions on the use of borates in the paints and coatings industry may be expected to be minimal.

### **7.2.3 Use in Mattresses**

For use in mattresses, it is concluded that although the consumer product (article) contains borates (boric acid), the application of the borate to the cotton batting will be undertaken by professionals as will the incorporation of the batting into the mattress. Thus, this use of borates is unlikely to be covered by any potential restrictions in any event.

More generally, given the importance of borates as a fire retardant and the low level of associated risks, there would be merit in considering a derogation (should any restrictions be proposed) for the use of borates as (primarily) a fire retardant.

#### **7.2.4 Use of Borates in Glass**

Borates are used in a range of glass, glass fibres and glass products where they increase the mechanical strength of glass, as well as their resistance to thermal shock, chemicals and water. It is estimated that around 335,000 tonnes of borates are used in glass and glass products and ceramics. Information provided by APFE (representing glass fibre producers) suggests that over 84,000 tonnes of borates are used by its members to manufacture glass products while EURIMA (representing insulation manufacturers) estimates that around 80,000 tonnes of borates are used in the manufacture of around 3.6 million tonnes of end-product.

In recent years, the boron content in glass has gradually been reduced from 8-10% B<sub>2</sub>O<sub>3</sub> (or 2.5-3% boron) by weight to around 5% (1.5% boron); although the concentrations are much higher in some specialised applications. However, it is considered that the presence of borates in glass products is extremely unlikely to result in any significant exposure of borates to consumers using such products. Furthermore, since the borates are chemically bound into a crystal lattice of inter-connected oxide molecules to form a substance, glass would not be the subject of restrictions relating to preparations/mixtures containing borates.

In any event, information provided from glass producers and their trade associations indicates that there are currently no known viable alternatives to the use of borates in the manufacture of borosilicate glass or indeed, mineral wool insulation products. Since borates are an integral component for glass fibre manufacturing, a loss of borates would mean that fibre glass products could no longer be manufactured.

### **7.3 Impacts on Manufacturers, Importers and Suppliers**

Borates are not mined (significantly) within the EU-27 and the vast majority of borates consumed must be imported into the EU as raw or refined materials or in the form of finished products. Most imports are from Turkey and the USA and the top five importers in the EU are Belgium, Germany, Netherlands, Spain and France.

Based on the information provided, it is estimated that around 600,000 tonnes of borates are supplied to the EU per annum. Although the market appears to have been reasonably stable in the last five years, there has been a reduced demand for sodium perborate (used as bleach in detergents). However demand has increased in most application areas, particularly in agriculture and vitreous (or selected high temperature) applications (such as insulation fibre glass (IFG), borosilicate glass and frits & ceramics).

Assuming that the potential restrictions result in the loss of market in uses accounting for 10-25% of current tonnages in total, the total value of lost sales and revenue is estimated at between **€18 million and €45 million per annum**. The actual economic loss to the EU borates industry would, however, be between **€900,000 and €2.5 million per annum** (where this reflects the actual profit margin after removal of production costs, operational

costs, etc.). It is worth noting that most of the importers/suppliers of borates are SMEs which may be impacted more heavily than larger companies. Any wider impacts cannot be stated with certainty at this point.

## 8. REFERENCES

- AISE (2008): **Re: Proposed Restrictions on Consumer Products containing Borates**, Letter Sent to RPA by the **International Association for Soaps, Detergents and Maintenance Products**(AISE), dated 16 May 2008.
- APFE (2008): **Questionnaire Submission to RPA**, Personal Communication with the **European Glass Fibre Producers Association** (APFE), June 2008.
- APFE (2003): **Continuous Filament Glass Fibre and Human Health**, European Glass Fibre Producers Association, dated July 2003 and available from PPG Industries (and elsewhere): [corporateportal.ppg.com...](http://corporateportal.ppg.com...)
- ATSDR (2007): **Draft Toxicological Profile for Boron**, US Agency for Toxic Substances and Disease Registry, draft dated September 2007.
- Baumann MGD & Conner AH (1994): *Carbohydrate Polymers as Adhesives* in **Handbook of Adhesive Technology** (Eds: Pizzi A & Mittal KL), New York, Marcel Dekker Inc.
- Borax (2008): **Borates in Industrial Fluids**, Article Downloaded from the **Borax Website**: [www.borax.com/pdfs/Industrial\\_Fluids.pdf](http://www.borax.com/pdfs/Industrial_Fluids.pdf)
- Borax (1998): *Surfing Waves and Web on Borosilicate Glass*, Pioneer, (RioTinto) Borax in-house magazine.
- BAC (2007): **Trends and Prospects in International Trade in Borates, Peroxoborates (Perborates)**, Market Survey prepared by Business Analytical Center dated November 2007.
- CEC (2006): **Commission Decision of 03.05.2006 Relating to a Proceeding Pursuant to Article 81 of the EC Treaty and Article 53 of the EEA Agreement (case comp/f/38.620 – Hydrogen Peroxide and Perborate)**, Commission of the European Communities, Brussels, 03.05.2006 c(2006) 1766 final.
- CEFIC (2008): **Questionnaire Submission to RPA**, Personal Communication with **CEFIC**, June 2008.
- CEFIC (2005): **CEFIC Position with Regard to the Proposed Classification and Labelling for Toxicity to Reproduction Endpoints of Sodium Perborate (CAS No. 11138-47-9)**, Submission to RPA by the CEFIC Peroxygens Sector Group, dated 4 February, 2005.
- CPIV (2008): *Panorama of the EU Glass Industry for 2006*, statistics from the Standing Committee of the European Glass Industries (CPIV), available from [www.cpivglass.be](http://www.cpivglass.be)
- CPSC (2006): **Quantitative Assessment of Potential Health Effects from the Use of Fire Retardant (FR) Chemicals in Mattresses**, report prepared by the US Consumer Product Safety Commission, dated January 2006.
- Dickson MH & Fanelli M (2004): *What is Geothermal Energy?* paper dated February 2004 and available on the International Geothermal Association's website: [iga.igg.cnr.it/index.php](http://iga.igg.cnr.it/index.php)



EBA (2008): **Questionnaire Submission to RPA**, Personal Communication with the **European Borates Association** (EBA), June 2008.

EBA (2008a): Information downloaded from the European Borates Association website.

EURIMA (2008): **Questionnaire Submission to RPA**, Personal Communication with the **European Insulation Manufacturers Association** (EURIMA), June 2008.

European Commission (2006): **Boric Acid** (May 2006); **Disodium Tetraborates** (June 2006); **Boric Oxide** (June 2006); **Disodium Octaborate Tetrahydrate** (June 2006), Draft Evaluation Reports by the Rapporteur (the Netherlands) for substances to be included in Annex 1 to the Biocidal Products Directive (available from DG Environment website).

European Food Safety Authority (2004): *Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Boron (Sodium Borate and Boric Acid)*, The EFSA Journal (2004) 80, pp1-22.

Eurostat (2008): *Statistical Classification of Products by Activity in the European Economic Community, 2008 Version*, as implemented by **Regulation (EC) No 451/2008** of 23 April 2008 and available from [ec.europa.eu/eurostat/ramon...](http://ec.europa.eu/eurostat/ramon...)

EVM (2003): **Safe Upper Levels for Vitamins and Minerals**, report issued by the (UK) Expert Group on Vitamins and Minerals, dated May 2003.

FEFCO (2008): **Questionnaire Submission to RPA**, Personal Communication with the **European Federation of Corrugated Board Manufacturers** (FEFCO), June 2008.

FEICA (2008): **Submission to RPA**, Personal Communication with the **Association of European Adhesives and Sealants Manufacturers**, (FEICA), June/July 2008.

Helvacı C & Alonso R (2000): *Borate Deposits of Turkey and Argentina: A Summary and Geological Comparison*, Turkish Journal of Earth Sciences, Vol 9, pp 1-27.

HERA (2002): **Perboric Acid, Sodium Salt, Mono and Tetrahydrate CAS No: 11138-47-9 (10332-33-9; 10486-00-7)**, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, draft dated August 2002.

HERA (2005): **Boric Acid (CAS No 10043-35-3)**, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, draft dated December 2005.

IFC (2007): **Environmental, Health & Safety Guidelines for Ceramic Tile and Sanitary Ware Manufacturing**, International Finance Corporation (World Bank), dated April 2007.

IMA (2008): **Borates**, Article downloaded from the **Industrial Minerals Association** (IMA) North America Website: [www.ima-na.org/about\\_industrial\\_minerals/borates.asp](http://www.ima-na.org/about_industrial_minerals/borates.asp)

Mantzou L & Capros P (2006): **European Energy and Transport: Trends to 2030 - Update 2005**, report prepared for DG Energy & Transport.

Murray FJ (2005): Risk Assessment of Mattresses with Borate-Treated Cotton Batting Before and After the Roller Test, report prepared for Jones Fiber Products dated August 2005.

- NCBI (2004): **What to Know about Cotton Batting**, pamphlet prepared by the (US) National Cotton Batting Institute ([www.natbat.com](http://www.natbat.com))
- RPA (2006): **Non-surfactant Organic Ingredients and Zeolite-based Detergents**, report prepared for DG Enterprise & Industry by Risk & Policy Analysts, dated June 2006.
- RTM (2008): **Information on Cellulose Insulation**, Information received from two companies via Rio Tinto Minerals (RTM), dated 4 July 2008.
- Schoeman MW and Lloyd JD (1999): **The Role of Boron-based Additives in Exterior Wood Coatings**, *Journal Surface Coatings International Part B: Coatings Transactions*, Volume 82, Number 3, March, 1999.
- UEIL (2008): **Re: Questionnaire for Downstream Users**, Letter Sent to RPA by the **Independent Union of the European Lubricant Industry** (UEIL), dated 29 May 2008.
- UKCPI (2008): **Proposed Restrictions on Consumer Products containing Borates**, Letter Sent to RPA by the **UK Cleaning Products Industry Association** (UKCPI), dated 20 May 2008.
- Umweltbundesamt (2007): **Perboric Acid, Sodium Salt**, (Revised) EU Risk Assessment Report prepared by the Austrian Federal Environment Agency, dated November 2007.
- US EPA (2002): **Life Cycle Assessment of Desktop Computer Displays: Summary of Results**, Report EPA/744-R-01-005, dated March 2002.
- US EPA (2004): **Toxicological Review of Boron and Compounds**, report by the US Environmental Protection Agency, dated June 2004 and available from [www.epa.gov/ncea/iris](http://www.epa.gov/ncea/iris).
- USGS (2007): **2006 Minerals Yearbook - Boron**, US Geological Survey, October 2007.
- Wakelyn PJ *et al* (2003): *Cotton Batting Fire-Blocking Barriers for Soft Furnishings*, paper presented to the 14<sup>th</sup> Annual BCC Conference on Flame Retardancy, Stamford (USA), 3 June 2003 (available from [www.natbat.com/fireblock.pdf](http://www.natbat.com/fireblock.pdf))
- Wallenberger FT *et al* (2001): *Glass Fibers*, from the ASM Handbook produced by the ASM Community ([www.asminternational.org](http://www.asminternational.org)).
- Yao *et al* (2006): **Borate Esters Used as Lubricant Additives**, *Lubrication Science*, Volume 14, Issue 4, pages 415 - 423, 7 March 2006





**ANNEX 1**

**(EXTRACTS FROM)**

**PROJECT SPECIFICATION**

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## **ANNEX 2**

### **SUMMARY OF BORATES UNDER STUDY**





## **ANNEX 3**

### **LIST OF CONSULTEES**



## **ANNEX 4**

### **USE OF BORATES IN GLASS AND GLASS FIBRE**



## **ANNEX 5**

### **USE OF BORATES IN OTHER APPLICATIONS**

