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Etimine S.A. Comments to the European Commission's Consultation on the 6th Priority List of Substances for Inclusion in Annex XIV 27 November 2014

Etimine S.A., the only representative of Turkish borates produced by Eti Maden IGM in Turkey and placed on the EU market, welcomes the opportunity to submit comments through the call for information by the European Commission on the ECHA's draft recommendation for inclusion of boric acid (EC 233-139-2), disodium tetraborates (EC 215-540-4) and diboron trioxide (EC 215-125-8) in the 6th prioritisation list for inclusion in Annex XIV.

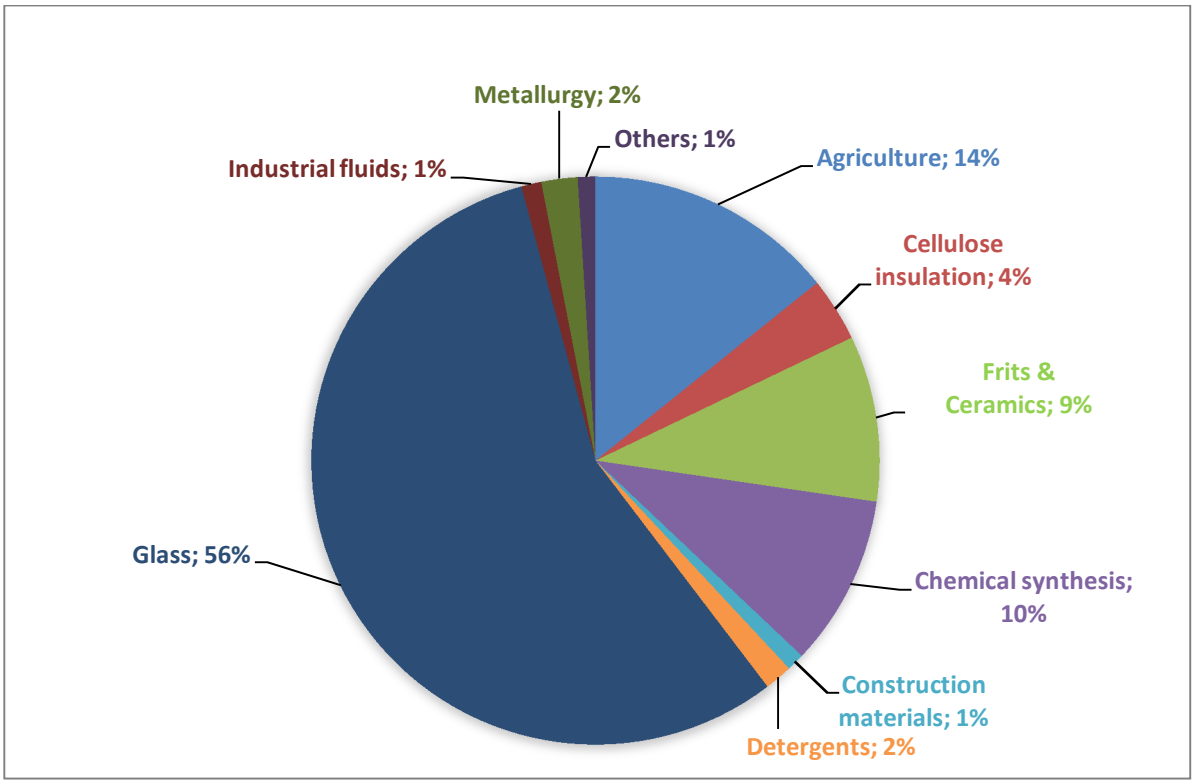
The figures provided in this submission refer to 2012 data on which the most recent (January 2014) update of the REACH registration dossiers of boric acid, disodium tetraborates, and diboron trioxide are based. Etimine S.A. represents the companies placing on the market more than 50% of the total tonnage (of the total of boric acid, disodium tetraborates and diboron trioxide) imported into the EU.

Etimine S.A. does not support the inclusion of boric acid, disodium tetraborates and diboron trioxide in the draft ECHA 6th prioritisation list for Annex XIV. Despite the identification of a/m substances as SVHCs, borates are safe for the general public and for workers. A number of recent epidemiological studies have shown the absence of health effects for the general public and even for highly exposed workers.

USES

Etimine S.A. is the only representative of Turkish borates produced by Eti Maden IGM in Turkey and placed on the EU market. Our REACH registration dossiers for boric acid, disodium tetraborates, and diboron trioxide cover all the imported tonnages of these substances from Turkey to the EU. The following chart shows uses of the Turkish borates (boric acid, disodium tetraborates, and diboron trioxide) in the EU:

Graph-1: Use of Turkish Boric Acid, Disodium Tetraborates and Diboron Trioxide in the EU (Source: Etimine S.A., the only representative of Eti Maden IGM).



The major uses of the mentioned Turkish borates in the EU are outside the scope of authorisation, either as intermediates or as mixtures below the specific concentration limit (SCL), or covered by other legislation.

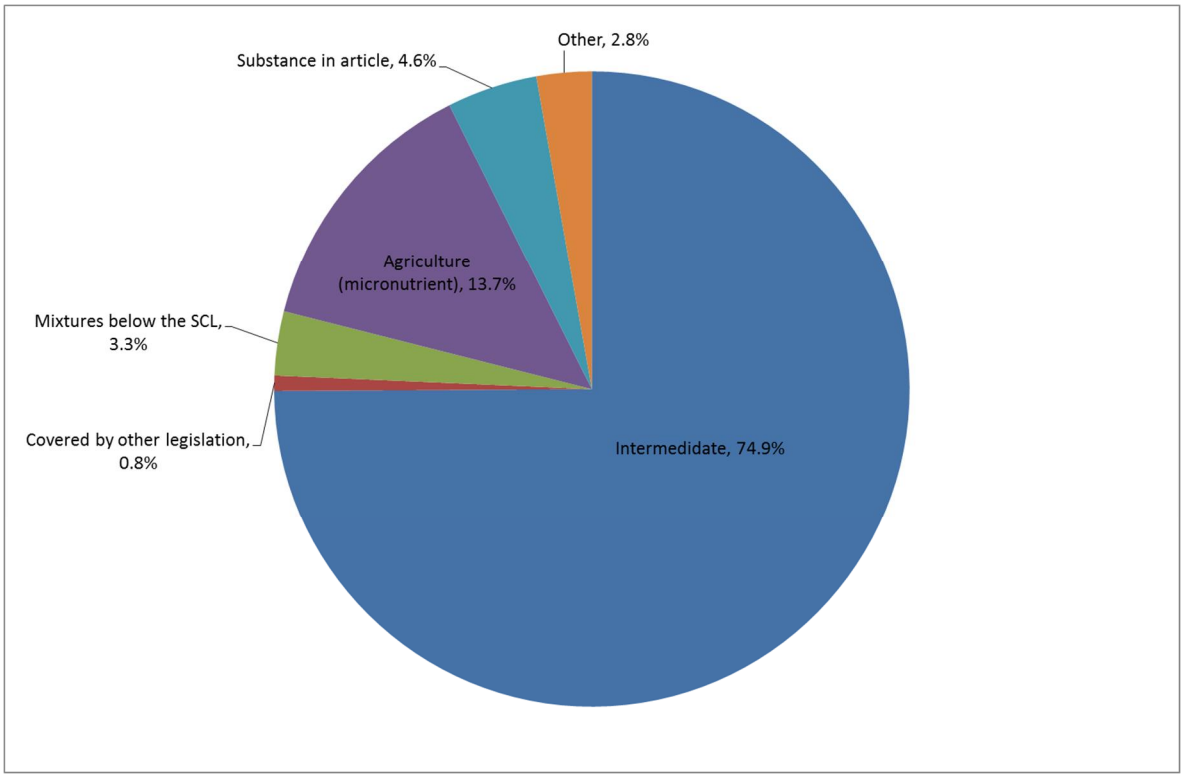
About 80% of the Turkish boric acid, disodium tetraborates, and diboron trioxide used in Europe is outside the scope of authorisation, as these substances are mainly:

- used in the manufacture of glass and frits or for the synthesis of new substances: in these uses, the substances qualify as an intermediate since they are completely consumed and transformed into another substance. In the new substance formed, boron is part of the chemical structure and thus, these uses fall outside the scope of authorisation.
- used in mixtures below the specific concentration limits.
- covered by other sector-specific legislation (e.g. biocides), again, falling outside the scope of authorisation.

In compliance with the Etimine S.A. data, the remaining one-fifth is used in the EU in agriculture (13.7%), in articles (4.6%) and other uses (2.8%) such as coatings, industrial fluids or metallurgical applications according to the REACH Borates Consortium data (see Graph-2).

The consolidated data from the REACH registration dossiers illustrates the overall European use of boric acid, disodium tetraborates and diboron trioxide as follows:

Graph-2: Uses of Boric Acid, Disodium Tetraborates, and Diboron Trioxide in the EU (Source: The EBA, European Borates Association).



Apart from the 80% of the uses falling outside the scope of authorisation, we would like to point out that, boron is irreplaceable in following uses:

Use of Boron in Agriculture is to be exempt from Authorisation due to Bio-essentiality

Boron is an essential micronutrient for normal, productive plant growth and is one of seven essential micronutrients for plants according to the EU Fertiliser Regulation (2003/2003/EC). The use of boron in fertilizers, present as these substances, accounts for about 14% of the boric acid and disodium tetraborates and diboron trioxide entering the EU market.

The use of boron in agriculture is well below the specific concentration limit. Therefore this use should be exempt from authorisation in accordance with REACH Article 56.6(b). In addition to the essentiality point of view, one should bear in mind that borates also reduce the amount of pesticides used in agricultural applications.

Nuclear Safety

The use of boric acid in nuclear power plants is essential for safety reasons. The natural boron isotope, ^{10}B, is required and cannot be substituted. Thus, the use of borates in nuclear power plants should be exempt from authorisation.

Safe uses of Borates

Although reproductive and developmental effects have been demonstrated in laboratory animals exposed to abnormally high doses of boric acid, similar effects have not been observed in studies of highly exposed human populations or workers exposed to over 100 times the general population for many years. As the REACH registration dossiers of boric acid, disodium tetraborates and diboron trioxide has recently been updated to this end, the absence of adverse reproductive effects in extensive investigations of borate workers in the United States, China, and Turkey chronically exposed to high levels of borates and in populations living in high boron areas demonstrate that maximal possible exposures in humans are insufficient to cause reproductive toxicity effects. Furthermore, there is no evidence of developmental effects in humans attributable to boron in studies of populations with high exposures to boron either. Besides, we know that with the exposure scenarios we provide our downstream users with (by means of the e-SDSs) workers and the environment are already adequately protected from exposure to borates not only at our warehouses in the EU, but also at the level of the European end-users.

SUBSTITUTION

Taking into account the socio-economic importance of borates and the fact that no substitutes are available for the most important uses, Etimine S.A. is not aware of any R&D work in attempt to substitute either boric acid or disodium tetraborates or diboron trioxide. Besides, we are not interested in any R&D study for substitution of our substances, since we know that our substances are safe. However, we are aware of a number of cases that the borates substitute others. Some recent examples can be given as follows:

One of the good examples to the irreplaceability of borates (in particular the boric acid and/or disodium tetraborates) is the recent Annex XV proposal of France to restrict the use of inorganic ammonium salts in production of cellulose insulation materials. Having the primary function of flame retardancy and the secondary function of biocidal effect at the same time, borates have a critical role in cellulose insulation manufacturing. As Etimine S.A. is officially informed by ECHA[1] to participate in their public consultation for this specific

[1] It is stated in the ECHA letter we received on 01.09.2014 that "*ECHA launches a public consultation on a proposed restriction of inorganic ammonium salts in cellulose insulation materials. You have previously submitted a registration dossier to ECHA for boric acid/sodium tetraborates. We would like to inform you that the public consultation on an Annex XV restriction report for inorganic ammonium salts is started on 18 June 2014 and will last for 6 months concluding on 18 December 2014 and the substance you have registered has been identified as an alternative to inorganic ammonium salts. ECHA's Risk Assessment Committee (RAC) and Committee for Socio-Economic Analysis (SEAC) will take your comments into account in their opinions on the proposed restriction.*"

issue, in their Annex XV dossier, now boric acid/disodium tetraborates are shown by France as a substitution to the inorganic ammonium salts for the production of cellulose insulation materials.

Boric acid is considered as one of the substances on the aerospace industry's radar – see the Q&A from the link: http://www.boeingsuppliers.com/environmental/reach_qa.html . Boric sulfuric acid anodising was developed by Boeing as an environmentally-preferred replacement for chromic acid anodising (please refer to the article "Avoiding turbulence", ChemicalWatch, Issue 70 – September 2014, Page: 2). Further information can also be seen from the link http://www.anoplate.com/finishes/anodizing.html that states Boric-Sulfuric Acid Anodize (BSAA) as an alternative to chromic acid anodize (CAA) due to the environmental, worker safety and health concerns and the related costs associated with continued use of hexavalent chromium-bearing processes such as CAA.

According to the article "Lead-Free Glass Decoration" in the GAE, Glass Alliance Europe, *Newsletter N°312, October 2014, page: 52,* Fraunhofer researchers have developed printing inks for glass that do not contain any toxic elements. Whether on baby bottles, beer mugs or perfume bottles, imprints on glass consist mainly of lead oxide. A new development by researchers at the Fraunhofer Institute for Silicate Research ISC in Würzburg and the Forschungsgemeinschaft Technik und Glas e.V. FTG addresses this issue resulting in lead oxide free decorative paints, replacing toxic substances previously used. They are easy to process, have high colour brilliance and are chemically resistant. In addition, they do not contain any rare or expensive elements. The basis of these novel decorative paints is a glass that consists mainly of zinc oxide. Further constituents are aluminum oxide, boron oxide (diboron trioxide) and silicon dioxide.

MARKET AND SUPPLY CHAIN

Turkey has almost three-fourths (about 73%) of the world's total boron reserves.

Eti Maden is the global leader of the boron sector. Employing about 7000 people, the exclusive Turkish State Enterprise, Eti Maden, has maintained its sectorial leadership for borates since 2005.

Exporting 97% of its boron products, Eti Maden is the biggest borate producer in the world and also has the largest share of the world boron market.

In the year 2012, the market share of Eti Maden in the world was about 46%.

Today, generating about 900 M US$ sales revenue, Eti Maden keeps its leadership in the boron market by supplying 47% of the world boron demand. Serving over 2800 customers, Eti Maden exports borates to over 100 countries and ships out its boron products over 380 destinations.

Through its subsidiaries, Etimine S.A. in Luxembourg, AB Etiproducts OY in Finland, the sub agent Mario Pilato Blat SA in Spain and direct sales to some near Member States (i.e. Greece, Bulgaria, etc.), Eti Maden has a market share in the EU of more than 50% for boric acid, disodium tetraborates, and diboron trioxide in total.

COMPETITIVENESS

Etimine S.A. is a placer on the market and an importer at the same time. It is a company dealing with borates only; thus, if the substances are not on the market, we are not there either.

The significance of boric acid, disodium tetraborates and diboron trioxide with regard to the global competitive position of EU firms is that if our downstream users are not able to use our substances in their production processes, they will not be able to compete with non-EU firms in terms of quality and productivity.

It is inevitable that listing boric acid, disodium tetraborates and diboron trioxide in the Annex XIV will have following increased effects in terms of the cost and price competitiveness:

- Consumption of energy,
- Loss of productivity,
- Increased overall cost.

The likely impact of including boric acid, disodium tetraborates and diboron trioxide in Annex XIV on the competitive position of the European downstream users with respect to non-EU competitors, in particular, for the main uses where substitutions are not available, it would certainly cause closing down or relocation of most of the economic activities outside the EU.

As we supply mainly to the global companies, the relocation will certainly happen; they will move the production to non-EU sites. The distortion of competition will be important as countries outside the EU (i.e. Switzerland, Norway, Russia, Turkey, etc.) will, without any constraints, be able to produce mixtures (such as some fertilizer formulations) and place them as a final product with concentration below the SCL on the European market.

There are non-EU competitors in the world, who will still be allowed to use boron, therefore, technically be able to produce less expensive with at least the same quality. Our main downstream users will be able to move easily. This basically means that small local EU companies will suffer and die. For those who have to produce locally, cost will increase and the end users will suffer.

Individually or together, if boric acid, disodium tetraborates, and diboron trioxide are included in Annex XIV, there will be no gain, but only loss and some uncertain R&D.

To our knowledge, the inclusion of boric acid, disodium tetraborates and diboron trioxide in Annex XIV will not trigger the investment in R&D (substitution efforts) in the industry sector.

Our products are key elements and a lot of R&D works have either been done or being done in production processes. Authorisation will not necessarily increase any R&D studies in this respect.

The cost of work to comply with the regulatory issues also affects the competitiveness. In case of Annex XIV listing, there will certainly be a decline in import of boric acid, disodium tetraborates and diboron trioxide to the European countries.

For the downstream users, moral effect has to be taken into consideration, since the increased uncertainty will impair the investment climate as well.

APPLICATION FOR AUTHORISATION

We will do our best to support as much uses as possible by considering applying for an authorisation if boric acid, disodium tetraborates and diboron trioxide are included in Annex XIV; but, in case of negative considerations, many sectors that are not able to afford the burden will certainly die. The sectors that are the most boron dependent but consumed less are the most vulnerable ones.

REGULATORY OPTIONS - *EU Legislative aspects*

A Risk Management Options analysis (RMOa) should be conducted for the recommended borates before a decision can be taken on the appropriate regulatory instruments.

The implementation of the SVHC Roadmap allows substances with potential concerns to benefit from an RMOa in order to identify the most appropriate risk management options. This is welcomed by Industry as it would improve regulatory effectiveness and proportionality. To our knowledge, an RMOa has not been carried out for borates. Recognizing the experience from the 5th list recommendation and the nature of the other substances that have been put forward in the 5th and 6th lists, we would strongly recommend assessing the efficiency and proportionality of authorization in order to consider whether this is the right RMO for borates. Such an analysis would potentially avoid using unnecessary administrative-, financial- and other resources of the Competent Authorities, the EU institutions and the user industries of borates, many of which are Small- and Medium- sized Enterprises.

We believe that workers are already adequately protected from exposure to borates. However if the EU wants to put in place additional control measures, one potential tool could be the establishment of Occupational Exposure Limit Values (OELVs) under the Chemical Agents Directive (98/24/EC). However, we are aware that the European Commission and Competent Authorities are currently discussing the relationship between REACH and workers protection legislation and potential improvements to the functioning of the latter, so the potential of using this regulatory instrument for borates would require additional consideration as part of an RMOa.

Simplification/streamlining authorisation would apply to borates.

In her speech[2] delivered on 12 November 2014 at the EPC-EESC conference on 'A New Industrial Policy for Europe', the Commissioner Elżbieta Bieńkowska emphasized that *"…In chemicals, we have to work on improving the implementation of REACH, especially as regards the authorization procedure…*". With this in mind, Etimine S.A. fully supports the Commission approach on streamlining and simplifications of the authorization process for some specific cases as detailed in the CARACAL document CA/81/2014. A number of non-exempted uses of borates would benefit from this approach if it were determined that authorization was the appropriate regulatory option.

CONCLUSION

In our view, using the REACH authorisation process to put in place additional controls of the recommended borates would not be proportional and would not contribute to regulatory effectiveness, particularly since ECHA's main concern appears to be workers' safety. Since the vast majority of the volume imported or manufactured borates is outside the scope of authorization or is irreplaceable, the large majority of workers would not benefit from additional protection through authorisation. At the same time, the authorisation of borates would require the use of administrative, financial and other resources from the Competent Authorities, the EU institutions and the suppliers and downstream user industries of borates. Taking into account the profiles of the other substances that ECHA has put forward for prioritisation in the 5th and 6th lists, and the current discussion on the streamlining and simplification of the authorisation process, prioritising boric acid, disodium tetraborates, and diboron trioxide now would not be appropriate. However, since a Risk Management Option analysis has never been done for borates (to our knowledge), we would suggest that such an analysis should be conducted before taking any further action on borates to establish whether additional controls are indeed required and if so, which regulatory instrument would be most effective to achieve this.

[2] Elżbieta Bieńkowska, 'An EU industrial policy fit for the 21st century', EPC-EESC conference on "A NEW INDUSTRIAL POLICY FOR EUROPE", Brussels, 12 November 2014 (SPEECH/14/1680)

In conclusion, it is the position of the Etimine S.A. that the authorisation procedure will not lead to additional protection for workers and consumers. Taking into account the socio-economic importance of borates and the fact that no substitutes are available for the most important uses, means that prioritising boric acid, disodium tetraborates, and diboron trioxide at this time does not represent regulatory effectiveness and is not proportional.

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