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Member of IMA-Europe

EBA comments to the ECHA consultation on the 6th priority list of substances for inclusion in Annex XIV

– 31 October 2014 –

The European Borates Association (EBA) welcomes the opportunity to submit comments to the ECHA consultation on the proposed inclusion of boric acid, disodium tetraborates and diboron trioxide (borates) in the 6th prioritisation list for inclusion in Annex XIV. The figures provided in this submission refer to 2012 data reported by the members of EBA. The EBA represents the companies that manufacture or import 95% of the boric acid, 100% of the disodium tetraborates and 94% of the diboron trioxide in the EU.

OVERVIEW

The EBA does not support the inclusion of borates in the draft ECHA 6th prioritisation list for Annex XIV. Despite the identification of certain borates as SVHCs, borates are safe for the general public and for workers. Several epidemiological studies show the absence of health effects for the general public and even for highly exposed workers. In our view, using the REACH authorisation process to control of borates would not be proportional and would not contribute to regulatory effectiveness.

ARGUMENTS AND RATIONALE

1. ***Consumers, industrial and professional workers are adequately protected by virtue of existing REACH restrictions or other EU regulations.***

    a. ***Consumers are adequately protected through the restrictions (REACH Annex XVII) and the risk management measures detailed in the exposure scenarios of the registration dossiers.***

In February 2012, the Commission adopted restrictions on borates ((EU) No 109/2012). Consequently, the use of borates in mixtures above the specific concentration limits is prohibited in consumer markets since 1 June 2012. An assessment of the impact of these restrictions should be conducted first before considering other regulatory options such as authorisation. The use of mixtures containing borates below the specific concentration level does not raise concern as consumers are not subject to prolonged exposure to borates and the threshold level for health effects observed in animals cannot be reached.

    b. ***Risks for workers are adequately controlled through the risk management measures detailed in the exposure scenarios of the registration dossiers and other chemical management legislation***

The REACH registration dossiers for diboron trioxide, boric acid and disodium tetraborates identified Risk Management Measures (RMM) where appropriate to ensure that health risks to workers are adequately controlled. RMM are communicated via the eSDS (extended Safety Data Sheet), which allows the site risk assessment to be carried out as required by the Chemical Agents Directive (98/24/EC); these mechanisms assist in ensuring worker safety. Additionally other downstream

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legislation specifically protects certain vulnerable workers from exposure to substances toxic to reproduction, such as pregnant workers (Dir. 92/85/EC) and young workers (Dir. 94/33/EC).

Further, for all identified uses, a Risk Characterisation Ratio (RCR) < 1 was determined and compliance with the DNELs can be achieved with common hygiene measures, i.e. without a need to use Personal Protective Equipment (PPE). This results from the low potency hazard of borates.

c. Total weight of evidence, including worker exposure data, shows that it is improbable that borates will cause reproductive and developmental effects in humans

Although reproductive and developmental effects have been demonstrated in laboratory animals exposed to abnormally high doses of boric acid, similar effects have not been observed in highly exposed human populations or workers. The absence of adverse reproductive effects in extensive investigations of borate workers in the United States, Turkey and China chronically exposed to high levels of borates and in populations living in high boron areas demonstrate that the actual health risk from exposure to borates is low. Workers in boron mining and processing industries represent the maximum possible human exposure. Based on the total weight of evidence that includes worker exposure data, epidemiological studies and mechanistic data, the data show that it is improbable that boric acid will cause reproductive or developmental effects in humans.

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

Nearly 79% of diboron trioxide, boric acid and disodium tetraborates used in Europe is outside the scope of authorisation, as these substances are mainly used in:

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

3. Boron is irreplaceable in certain uses

a. Bioessentiality – should be exempt from Authorisation

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 accounts for about 13.7% of the diboron trioxide, boric acid and disodium tetraborates entering the EU market. More detail on this aspect was provided in EBA's submission to ECHA's public consultation on 2 October 2014.

Acknowledging the essentiality of boron for agriculture, the authorisation would have to be granted for agriculture and would not achieve the aim of authorisation. It would become a "tax system".

Thus, we are of the opinion that the use of borates in fertilisers should be exempt from authorisation.

b. Essential for 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, as the authorisation would in any case have to be granted and would not contribute to the aim of authorisation under REACH.

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

The implementation of the SVHC Roadmap allows substances with potential concerns to benefit from an RMOa in order to identify the most appropriate risk management options. This is welcomed by Industry as it would improve regulatory effectiveness. To our knowledge, an RMOa has not been carried out for borates. Recognising the experience from the 5th list recommendation, we would strongly recommend assessing the efficiency of authorisation in order to consider whether this is the right RMO for borates.

5. Grouping is only effective when all substances of the group are prioritised at the same time.

In previous evaluations (2011, 2012) on prioritisation of SVHCs, ECHA suggested "grouping other boron compounds from the candidate list to prevent replacement of the authorised substances by other similar substances". The EBA agrees that the grouping approach should be used to (i) avoid duplicating the administrative burden and (ii) ensure an equal playing field. Should borate substances be recommended for prioritisation in the future (despite our arguments against this step), we consider it appropriate to suggest that all borate substances classified as Repr 1B H360FD be grouped.

Today diboron trioxide, boric acid and disodium tetraborates are identified as SVHCs. In March 2014, the RAC recommended the classification & labelling of disodium octaborate and disodium octaborate tetrahydrate as Repr 1B H360FD, yet these are not considered SVHCs at this point. We believe these substances could replace diboron trioxide, boric acid and disodium tetraborates in a number of end uses. This situation should be clarified before considering prioritisation of other borates for inclusion in Annex XIV.

In conclusion, it is the position of the EBA 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 borates at this time does not represent regulatory effectiveness and is not proportional.

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