29 NOVEMBER 2012

Responses to Comments Document (RCOM) on ECHA's Draft 4th Recommendation for Arsenic Acid (EC number: 231-901-9)

This document provides ECHA's responses to the comments received during the public consultation on the draft 4th recommendation for inclusion of substances in Annex XIV of REACH. In addition to this Response to Comments table, on ECHA's website there is available a zip-file including all attachments to the individual comments (as far as not confidential): http://echa.europa.eu/documents/10162/13640/axiv_rcom_arsenic_acid_attachments_en.7z

PUBLIC VERSION

CONTENT

I - General comments on the recommendation to include the substance in Annex XIV, including the prioritisation of the substance:

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
10	2012/09/19 21:36	European Environmental Bureau (EEB) International NGO Belgium	The EEB supports the inclusion of this substance in Annex XIV due to its hazardous properties, high production volumes and wide spread uses. It is also a substance that is included in the Trade Union Priority List and cause occupational diseases. The use of this substance in the market is having adverse consequences for public health and environment and should be banned at European level.	Thank you for your support and for giving your reasoning.
9	2012/09/19 21:21	ChemSec International NGO Sweden	We support the recommendation to include this substance in Annex XIV.	Thank you for providing your opinion.
8	2012/09/19 18:00	European Trade Union Confederation Trade union Belgium	ETUC supports the recommendation to include this substance in the authorisation list.	Thank you for providing your opinion.
6	2012/09/19 10:29	MSCA Sweden	We support the prioritisation of arsenic acid for inclusion in Annex XIV. The substance has relatively high priority due to relatively high volume and wide dispersive use. In addition, arsenic acid can be used to replace diarsenic trioxide, which has already been included in Annex XIV.	Thank you for your support and for giving your reasoning.
5	2012/09/18 18:06 See attachment *5_GAE REACH position paper on arsenic acid.pdf*	GLASS ALLIANCE EUROPE aisbl Industry or trade association Belgium	FUNCTION OF ARSENIC ACID IN THE PRODUCTION OF GLASS The Draft background document for Arsenic acid (Document developed in the context of ECHA's fourth Recommendation for the inclusion of substances in Annex XIV) dated from 20 June 2012 as published on ECHA's webpage, refers to Arsenic acid being "used as fining agent in the manufacture of speciality glass" (see page 2, point 2.2.2.2 of the above mentioned document).	Thank you for your comment. The use of arsenic acid in the in the manufacture of glass does not seem to be a use of the substance as an intermediate. According to Appendix 4 of the "Guidance on intermediates" (http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf) from December 2010, *"An isolated intermediate (i.e. a substance "used […] in order to be*

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			Furthermore the document states as follows: "Although in the registrations considered as use of the substance as an intermediate, this use of arsenic acid rather appears to be as a "processing agent", similar to the use of diarsenic trioxide (As2O3) in glass making (Annex XV, 2011; ECHA, 2010). In glass production arsenic acid has the same function as diarsenic trioxide (As2O3), i.e. fining agent. Both substances can and appear to be used interchangeably in the glass sector. For As2O3 it was concluded that there seem to be problems regarding occupational exposure control in (parts of) the glass industry although there is uncertainty about the extent (ECHA, 2010)." (see pages 2 and 3 of the above mentioned document). The document also refers to Arsenic acid and Diarsenic trioxide being used as fining agents to remove bubbles from the glass melt (see page 3, point 2.2.2.3 of the document). As will be shown in the following paragraphs, these statements do not display the role of Arsenic acid in the "synthesis" of speciality glass. Arsenic acid as well as Diarsenic trioxide (As2O3) and Diarsenic pentaoxide (As2O5) are used in the glass production as intermediates under the REACH Regulation. The nature of glass Glass is a substance of variable composition, which for simplicity is expressed by convention in terms of oxide of the constituent elements (the oxides: SiO2, Na2O, CaO, B2O3, etc). Although conventionally glass compositions are expressed as oxides of the different elements, glass is a non-crystalline or vitreous inorganic macromolecular structure, which does not show behaviour of the individual different raw materials or oxides. The individual raw materials undergo chemical reaction and are transformed into a silicate glass. The raw materials used to manufacture glass react to create a new chemical substance, totally different from the starting materials. Glass is not a mixture of compounds such as metals or oxides. The physico-chemical, toxicological and eco-toxicological properties of the substance glass are totally different from those	*transformed into another substance"), is used in the manufacturing of another substance where it is itself transformed into that other substance. […]* *Whenever a substance (A) used in a chemical processing is not used in the manufacturing of another substance (B) in order to be itself transformed into that other substance (B), it is necessarily used in order to achieve another function than transformation, either as part of the manufacturing of another substance (B) (e.g. as catalyst, processing agent, solvent), or as part of another activity (e.g. as an individual step in the production process of an article). While this other function may still involve chemical modification of the substance (A) used in the process, this type of use cannot be considered as the manufacturing of another substance (B) from the transformation of substance (A).* *Therefore, as soon as the main aim of the chemical process is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function, substance (A) used for this activity should not be regarded as an intermediate under REACH."* As stated in your comment glass is composed of oxides of silicon, sodium, calcium, and some other elements. However, arsenic acid is not a necessity for the manufacture of glass and it is not added in order to be itself transformed into that substance, i.e. the glass. Arsenic acid is rather used to achieve another function in the manufacturing process that is to remove bubbles from the glass melt (as stated in the background document and in your comment). It is in that function in which the chemical reaction process of arsenic acid takes place and not for the sake of synthesis of the glass as such. In conclusion, arsenic acid appears to be used as processing agent to modify the properties of glass (degassing) rather than for its synthesis. Consequently the substance cannot be considered as an intermediate in the sense of the definition set out in Article 3(15) of the REACH Regulation.

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			of the individual raw materials or oxides. Under REACH, glass is classified as a UVCB substance (substance of unknown or variable composition, complex reaction products or biological materials – Annex V (11) REACH). It is exempted from the REACH registration requirement under certain conditions laid down in Annex V (11) REACH. The flow chart of the production can be described as follows: Arsenic acid, as all the other raw materials used in the production (synthesis) of glass, reacts with other raw materials (substances) at high temperature to produce the new substance glass. During this process, the oxides from the raw materials form a new random network, where different elements are linked together by oxygen bridges. Arsenic acid is completely consumed during this chemical reaction and no longer contained as such in the final substance glass. Raw materials Glass substance Glass article The general chemical reaction to form silicate-glasses can be illustrated by the following simplified equation: a SiO2 [sand] + b Na2CO3 [soda] + c CaCO3 [lime] + d CaMg(CO3)2 [dolomite] + e Na2SO4 [sodium sulphate] + f Arsenic Acid….. → x SimNanCaoMgpAsf……Os) [glass] + y CO2↑ + z SO2 ↑ + O2 ↑ ….. Please note that the composition of glass is expressed by convention as oxides of the elements constituting the network. This does not mean that glass is a mixture of non-bonded different oxides. The physico-chemical properties of the new substance glass (chemical resistance, mechanical resistance, transmittance, colour, inertness etc.) are a function of the composition and the network formed. A different composition leads to a different glass	

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			(chemical / molecular) structure and consequently different physico-chemical properties of the final product. The function of arsenic acid in the production of glass Several chemical substances, so-called "glass formers" are able to form the network structure and thereby the glass. These are mainly inorganic chemical oxygen bounded substances such as silica, boron, germanium, phosphor and arsenic. Thus, arsenic compounds are considered as "glass formers". Arsenic acid is a raw material used to produce different kinds of glass, mainly domestic glass and special glass (e.g. pharmaceutical glasses, optical glasses, display glass, glass-ceramics,…). It participates in the chemical reactions to create the glass network and is completely consumed in the new substance glass (N.B.: the arsenic does not evaporate, and stays in the substance glass) and therefore contributes to the functional structure of the new substance. During the chemical reaction it contributes to the generation the oxygen bonds between the elements. In addition, by a redox reaction, it thereby also releases gaseous oxygen that helps to remove bubbles in the glass. Arsenic acid acts clearly as a precursor to make glass and it cannot be regarded just as an "auxiliary agent" (catalyst, processing agent, solvent). On a molecular scale arsenic acid enters the glass network as a tightly bonded constituent and therefore becomes an integral part of the glass structure. The presence of arsenic ions in the network structure confers unique properties to the glass such as a specific redox state, clarity, colour, transmittance, absence of bubbles, lack of inclusion, etc…, which are critical to the function of glass. Intermediate status of arsenic acid Raw materials that are used in the manufacture of glass meet the definition of transported isolated intermediates as they are	

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			produced elsewhere and transformed into a new substance (glass) at the glass manufacturers' site. In the case of Arsenic acid this can be further explained as follows: Arsenic acid (A) acts as raw material for glass (B) manufacturing. The structure of this (crystalline) substance (A) - crystallographically a well-defined cubic structure - is changed during the glass manufacturing process, where by means of a mineralogical transformation a stable non-crystalline, vitreous substance (B) is generated. The reason for the arsenic acid to be considered as an intermediate is that during the transformation another substance (glass) is synthesized. The glass network structure shows properties which differ totally from the sum of the properties of the individual raw materials. Arsenic acid acts as network former i.e. new chemical bonds are formed (with tetrahedral and/or trigonal chemical bonding could you refer to literature that indicates these types of bonding?) in the non-crystalline glass configuration and thus, arsenic acid is together with silica, boron oxide and for instance alumina a prime candidate for the glass synthesis. Therefore, it displays the features of an intermediate.	
2	2012/09/12 15:10	MSCA Norway	The Norwegian CA supports the prioritisation of Arsenic Acid for inclusion in Annex XIV.	Thank you for providing your opinion.

II - Transitional arrangements. Comments on the proposed dates:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
10	2012/09/19 21:36	European Environmental Bureau (EEB) International NGO Belgium	As soon as possible	Thank you for providing your opinion on this issue.
5	2012/09/18 18:06	GLASS ALLIANCE EUROPE aisbl Industry or trade association Belgium	AVAILABILITY OF ALTERNATIVES The background document refers to an input made by CPIV (now Glass Alliance Europe), saying that there are a number of applications in speciality glass that show technical difficulties in replacing arsenic (see background document p. 4, point 2.3). The document also refers to sodium/potassium nitrates with antimony trioxides as alternatives for arsenic in speciality glasses. Those substances can't be used for special applications where a very high glass quality is required. In the opinion of the European glass industries, it is also not advisable to replace a substance that possesses all required properties for a certain product, by another substance that is potentially harmful but degrading the glass quality level. The background document recognises this dilemma by saying: "Many of the alternatives to the use of arsenic in glass/enamel processing, e.g. antimony trioxide, may be considered potentially harmful to human health and the environment" (see p. 4 of the background document, point 2.3). A prioritisation of replacing or banning arsenic acid for the use in the (speciality) glass production is not rational, as it would result in the use of other potentially harmful substances in combination with products of inferior quality.	Thank you for your comment. The Authorisation title has three objectives, which according to Art. 55 are (i) the good functioning of the internal market and (ii) assuring that the risks from substances of very high concern (SVHC) are properly controlled and (iii) that these substances are progressively replaced by suitable alternatives or technologies where these are economically and technically viable. Information such as availability and suitability of alternatives should be provided as part of the application for authorisation, e.g. in the analysis of alternatives. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation. The meaning of "(suitable) alternative" in the context of authorisation means the possibility of replacement of the substance in a particular use by another in technical and economic terms feasible substance or technology, thereby reducing the overall risk arising from the use in question and concomitantly being feasible in technical and economic terms.

1	2012/09/06 10:52 See attachment *1_Remarks concerning paragraph 2.doc*	Company Luxembourg	Our proposal is the following: () sunset date 48 months if the use exemption is not accepted.	Thank you for your comment. Please note that REACH is an EU Regulation aiming to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. The obligation to apply for authorisation is to ensure that risks are adequately controlled or that socio-economic benefits are outweighing the risks, while concomitantly it is a strong incentive to search for and develop suitable alternatives. As arsenic acid is carcinogenic, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for arsenic acid will accordingly ensure that the health of workers in the EU involved in the uses of arsenic acid is protected. Please note further that authorisation, inter alia, is a means to promote the development of alternatives. Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, the present lack of alternatives to (some of) the uses of a substance and the need to complete R&D programmes to get qualified alternatives to it is no viable reason for adjourning the subjection of a substance or some of its uses to authorisation. Information regarding lack of alternatives is however important information for inclusion in an authorisation application. This information will be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

				The import of articles containing arsenic is indeed not directly affected by an authorisation requirement. After the sunset date defined in Annex XIV for a given substance, ECHA has the obligation under Article 69(2) to consider whether the use of that substance in articles poses a risk to human health or the environment and, if so, prepare an Annex XV restriction dossier.

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

#	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
9	2012/09/19 21:21	ChemSec International NGO Sweden	Being such a hazardous substance, no use should be granted a generic exemption from authorisation.	Thank you for providing your opinion on this issue.
7	2012/09/19 11:26	 Company France	Arsenic acid is used in labs as a standard for equipment calibration (routine analysis). Total volume used per year and per lab is very low (few grammes) and it is obvious that there is no alternative available. We then believe that the use of arsenic acid as an analytical standard in labs should be complely exempt from authorisation.	Thank you for your comment. Scientific research and development (SRD) is exempted from the authorisation requirement, according to Art. 56(3) REACH. We would suggest that you examine whether the mentioned use of arsenic acid can be regarded as SRD, in accordance with the definition set out in Article 3(23) REACH: *"(…) any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year*". Please, note that • SRD activities can cover analysis for monitoring or quality controls purposes; • Therefore, in principle a substance may be exempted from authorisation if used, on its own or in a mixture, in analysis for monitoring and quality control purposes, for instance, in order to monitor the presence or concentration of that substance or other substances; • Nevertheless, this exemption only applies to the extent

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				that the relevant operator uses that substance under controlled conditions[1] and in a volume less than 1 tonne per year; • Only substances used directly for research or analytical purpose, whether on their own, in mixture, or in conjunction with analytical equipments, can benefit from the SRD exemption. This excludes from the exemption any substances forming an integral part of an analytical device. If you conclude that your use of arsenic acid fulfils the above points, the use can benefit from the exemption of SRD from authorisation as set out in Article 56(3) REACH and no authorisation would be required to continue the use after the sunset date. Please refer also to response to Comment 3.
5	2012/09/18 18:06	GLASS ALLIANCE EUROPE aisbl Industry or trade association Belgium	AVAILABILITY OF ALTERNATIVES The background document refers to an input made by CPIV (now Glass Alliance Europe), saying that there are a number of applications in speciality glass that show technical difficulties in replacing arsenic (see background document p. 4, point 2.3). The document also refers to sodium/potassium nitrates with antimony trioxides as alternatives for arsenic in speciality glasses. Those substances can't be used for special applications where a very high glass quality is required. In the opinion of the European glass industries, it is also not advisable to	Please refer to Section II for response as same comment was given there.

[1] In the absence of explicit requirements set out by the competent authorities, the controlled conditions must be appreciated in relation to different elements including the intrinsic properties of the substance at stake, but also risk management standards. Although such standards may contribute to the determination of controlled conditions, their implementation may not alone be sufficient to meet this condition. Analytical activities that are not run under controlled conditions cannot benefit from the SRD exemption.

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			replace a substance that possesses all required properties for a certain product, by another substance that is potentially harmful but degrading the glass quality level. The background document recognises this dilemma by saying: "Many of the alternatives to the use of arsenic in glass/enamel processing, e.g. antimony trioxide, may be considered potentially harmful to human health and the environment" (see p. 4 of the background document, point 2.3). A prioritisation of replacing or banning arsenic acid for the use in the (speciality) glass production is not rational, as it would result in the use of other potentially harmful substances in combination with products of inferior quality.	
4	2012/09/18 14:06	Company Belgium	Arsenic acid is used in labs as a standard for equipment calibration (routine analysis). Total volume used per year and per lab is very low (few grammes) and it is obvious that there is no alternative available. We then believe that the use of arsenic acid as an analytical standard in labs should be complely exempt from authorisation.	See response to Comment 7
3	2012/09/18 13:53	Company Germany	We request an exemption for the formulation of standard solutions and the filling of arsenic acid into small packages for lab use. The industrial packaging/filling for the lab use is done by well trained personnel. The manufacturing of arsenic acid and the use of arsenic acid as analytical standard is exempted from authorisation (scientific R&D). Competitors directly importing the final analytical standard in small bottles for lab use would have a competitive advantage due to the fact that they would not need an authorisation. Consumers are not exposed to arsenic acid due to these uses. Arsenic acid is used in a preparation as an analytical standard for test and measuring instruments, e.g. as calibration standard for ICP and AAS by industrial and professional users. These applications are laboratory uses within the scope of scientific R&D. The risk for the environment and consumers is very low. Usually the volumes and the concentration of the substance are low. The filling/packaging of analytical standards for scientific R&D purposes should be exempted from authorisation, too.	Thank you for your comment. Please note that although uses for scientific research and development of a substance are exempted from the authorisation requirement in accordance with Article 56(3) this appears to only apply to its final use for SRD purposes under the conditions defined in Article 3(23). However, use of a CMR substance included in Annex XIV, on its own or in a mixture (above the lowest of the concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CLP Regulation)), for e.g. formulation of test kits or analytical standards with the intention to supply them for SRD purposes, would probably require authorisation. As arsenic acid is a carcinogen, there is a strong societal interest to protect humans, in particular workers handling the substance, from risks potentially arising from its uses. An authorisation requirement for arsenic acid will accordingly ensure that the health of workers in the EU

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				involved in the uses of this substance is protected. Please refer also to response to Comment 7.
1	2012/09/06 10:52	Company Luxembourg	The use of arsenic acid for the production of Copper Foil should be exempted for the following reasons: - The use of arsenic acid for the production of Copper Foil is limited to 2 companies in Europe, representing 3% to 4 % of the worlwide production of Copper foil. - The annual tonnage for this specific use can be estimated around 10t/year at European level (low tonnage band). - Data were provided in the registration file showing that workers exposure and environmental exposure are limited.	Thank you for your comment and the information you provided. As regards your request for exemption please note that uses (or categories of uses) can only be exempted from the authorisation requirement on the basis of Article 58(2) of REACH, unless they are already explicitly exempted in REACH Art. 2(5 & 8) and Art. 56(3 – 6). A list of generic exemptions from the authorisation requirement can be found on ECHA website: http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf An exemption based on Article 58(2) of REACH is possible only 'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'.[2]

[2] ECHA will consider the following elements when deciding whether to include an exemption of a use of a substance in its recommendation:

- There is existing EU legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definitions in accordance with Art. 3(24). Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- This EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria;
- This EU legislation imposes minimum requirements[2] for the control of risks of the use. Legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s) as relevant) are covered by the legislation.

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				The brought forward arguments as to why an exemption is requested for use of arsenic acid in the production of Copper Foil do not constitute a basis for exempting this use from authorisation based on Art. 58(2).

IV - Comments on uses for which review periods should be included in Annex XIV, including reasons for that:

#	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
5	2012/09/18 18:06	GLASS ALLIANCE EUROPE aisbl Industry or trade association Belgium	OCCUPATIONAL EXPOSURE AT THE WORKPLACE The background document also refers to occupational exposure saying: "Consumer exposure via articles resulting from the uses is considered to be insignificant but there might be potentially significant occupational exposure." (see page 5, point 3.1 of the background document).Occupational health is regulated in Member States by separate legislations, which provide sufficient safety standards to workers. Occupational exposure should therefore be regulated through such legislation as it is not a main task of the REACH Regulation. As the background document states correctly, consumer exposure via glass articles resulting from using the uses is insignificant. This is due to the scientifically proven and generally recognised inertness of the substance silicate glass. Accordingly, a prioritisation of arsenic acid resulting in an insertion in Annex XIV of the REACH Regulation is not justified.	Thank you for your comment. According to Article 58(3) REACH priority for inclusion in Annex XIV to REACH shall normally be given to substance with a) PBT or vPvB properties; or b) Wide-dispersive use; or c) High volumes. It is further noted that one of the objectives of the Authorisation Title of REACH is to assure that the risks from SVHCs are properly controlled. The *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation* describes the approach used in the prioritisation step and the background for this approach. http://echa.europa.eu/documents/10162/13640/axiv_prioritysetting_general_approach_20100701_en.pdf The approach has been discussed and broadly agreed by the Member State Committee. In cases, where the substance is identified because of hazards to human health, one of the aspects taken into account during the prioritisation step is whether there is potential for exposure of workers, consumers and/or humans via the environment. Therefore, the conclusion to give priority to arsenic acid for inclusion in Annex XIV is based on the currently available information justified.