ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF ARSENIC ACID IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: Arsenic acid

EC NUMBER: 231-901-9

CAS NUMBER: 7778-39-4

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Contents

Tables

About the report

This draft report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the substance in articles from various sources. Information is gathered (if available) from authorisations, applications for authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations and in substances in articles (SiA) notifications are also investigated. In order to gather information on possible uses of the substance in articles that were not identified during the screening phase, a call for evidence is launched via ECHA's website.

Risks stemming from the incorporation of the substance into an article are not in the scope of this investigation as it is assumed they were already addressed by the authorisation process[1]. For imported articles the incorporation process is carried out in third countries and therefore outside the scope of EU legislation, however imported articles are within the scope of this investigation. The incorporation is regarded to cover two type of uses[2]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements[3], while only few exemptions are envisaged in case of restrictions. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products and when a substance is used as an on-site isolated intermediate.

Based on the information gathered for [substance(s)], ECHA is of the view that there is no strong driver to prepare and submit an Annex XV restriction dossier at present. This draft screening Annex XV report is prepared to fulfil the requirements in article 69(2). A call for evidence is launched to gather further information and comments on the assumptions made in this draft report.

[1] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/qas Note that ECHA will investigate for this report whether applications for authorisation cover the incorporation of the substance into an article.

[2] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c

[3] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

A. Conclusions

A.1. Conclusions based on the assessment

Arsenic acid has been included on the candidate list (19/12/2011; ED/77/2011) and into Annex XIV of REACH (Commission Regulation (EU) No 895/2014 of 14 August 2014) with a sunset date of 22/08/2017. According to REACH, ECHA needs to consider whether the use of the substance listed in the Annex XIV in articles poses a risk to human health or to the environment that is not adequately controlled. In such cases, ECHA prepares a restriction dossier which conforms to the Annex XV to REACH.

ECHA has gathered information on the uses of arsenic acid in articles from various sources. This includes information gathered during the SVHC listing and recommendation for the inclusion of this substance in Annex XIV, uses identified in the REACH registrations and information in the submitted (1) application for authorisation, substances in articles (SiA) notifications and various external database searches. Following an assessment of the available evidence, there appears to be one EU use of arsenic acid to produce articles i.e. industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Board. An application for authorisation has been submitted and granted for this use[4]. Therefore, ECHA considers that there is no EU use of arsenic acid in articles that would lead to a non-adequately controlled risk that are not already regulated under REACH Authorisation. In addition based on available information mentioned above, there does not appear to be a presence of arsenic acid in articles being imported to the EU. Therefore, under Article 69(2), ECHA's view is that there is no strong driver for ECHA to develop and submit an Annex XV dossier for restriction at present. This is similar to the case of diarsenic trioxide and diarsenic pentoxide, which were previously assessed by ECHA (ECHA, 2016).

This conclusion will be tested in a call for evidence to last from 03/02/2021 to 17/03/2021.

Following this call the assessment will be reviewed and the conclusion sent to CARACAL as an information document.

It should be noted that like for other inorganic salts of metals, any hazard would likely come from the metal (arsenic in this case) and if arsenic were to be found in articles (e.g. following analytical analysis during an enforcement campaign), it would be difficult for enforcement authorities to know whether this would be coming from arsenic acid or different arsenic salts.

A.2. Targeting

This report is targeted on the potential release of arsenic acid from articles and exposure of arsenic acid when used in articles and whether or not such use should be restricted.

This targeting is based on the Article 69(2) of REACH Regulation that requires ECHA to consider if the use of the substance in articles is adequately controlled and prepare an Annex XV dossier

[4] https://ec.europa.eu/docsroom/documents/44426

for an appropriate restriction if this is not the case. The incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement[5].

A.3. Summary of the justification

A.3.1. Identified uses, hazard, exposure / emissions and risk

Information on uses

Based on the information gathered during the SVHC listing and recommendation for the inclusion of the substance in Annex XIV, uses identified in the REACH registrations and information in the received applications for authorisation, the (current and previous) uses of arsenic acid include:

- Intermediate use in the production of basic alloys
- Production of glass
- Production of copper foil for printed circuit boards

Information on hazards

Arsenic acid is included in Annex XIV based on its carcinogenic (category 1A) properties. Other endpoints are not relevant for this dossier.

Arsenic acid (and its salts) are classified in Regulation 1272/2008 (CLP) as: Carc. 1A H350; Acute Tox. 3 H331; Acute Tox. 3 H301; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

The opinion of the RAC on the evaluation of the occupational exposure limits (OELs) for arsenic acid and its inorganic salts (RAC, 2017) states that “Despite mechanistic indications of a threshold mode of action, the available data do not allow the identification of a threshold”.

Information on emissions/release/exposure

Not relevant - there is no use of the arsenic acid in articles that have the potential to lead to human exposure to arsenic acid.

Characterisation of risk

Not relevant - there is no use of these substances that would lead to a non-adequately controlled risk from arsenic acid concentrations in articles that are not already regulated under REACH authorisation.

A.3.2. Justification that action is required on a Union-wide basis

No restriction is proposed at present.

A.3.3. Justification that the proposed restriction is the most appropriate Union-wide measure

No restriction is proposed at present.

[5] Q&A ID No 564: https://echa.europa.eu/support/qas-support/qas?p_p_id=journalqasearch_WAR_journalqaportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=3

B. Information on hazard and risk

B.1. Identity of the substance and physical and chemical properties

B.1.1. Name and other identifiers of the substance

Arsenic acid

Chemical name: Arsenic acid

EC Number: 231-901-9

CAS Number: 7778-39-4

IUPAC Name: Arsenic acid

B.1.2. Composition of the substance(s)[6]

Arsenic acid

Chemical name: Arsenic acid

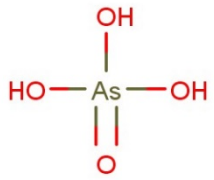
EC Number: 231-901-9

CAS Number: 7778-39-4

IUPAC Name: Arsenic acid

Molecular formula: AsH_3O_4

Structural formula: Source, ECHA



Molecular weight: 141.94

Typical proportion %: >80% (w/w)

Concentration range %: 90-100% (w/w)

[6] Synonyms can be found from Brief profile available on ECHA's website: https://echa.europa.eu/brief-profile/-/briefprofile/100.029.001

B.1.3. Physicochemical properties

Arsenic acid, anhydrous, CAS Nr. 7778-39-4 has not been isolated but is only found in solution where it is largely ionised. Its hemihydrate form, arsenic acid, hemihydrate ($As_2H_8O_9$), with CAS Nr. 7774-41-6 does form stable crystals.

Table 1: Physicochemical properties of arsenic acid

REACH ref Annex	Property	Value
VII, 7.1	Physical state at 20°C and 101.3 KPa	Liquid, solid
VII, 7.2	Melting / freezing point	35.5°C
VII, 7.3	Boiling point	160°C at 1013 hPa
VII, 7.5	Vapour pressure	12.58 hPa at 15°C
VII, 7.7	Water solubility	302 g/L at 12.5°C
VII, 7.8	Partition coefficient n-octanol/water (log value)	
XI, 7.16	Dissociation constant	pKa 2 = 7.089 +/- 0.01

Source: SVHC support document for arsenic acid (ECHA, 2011).

B.1.4. Justification for grouping

In the context of this article 69(2) screening, no group has been assessed; only the Annex XIV substance arsenic acid.

B.2. Manufacture and uses

B.2.1. Manufacture, import and export of the substance

According to the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012), arsenic acid was imported in a tonnage of 100-1000 t/y partly as aqueous solution in 2010. ECHA does not have more recent information on this imported tonnage figure (as of 10 December 2020).

No manufacture was reported at the time of the 4th recommendation. However, in 2014 a further transported isolated intermediate registration dossier was submitted, which included a "manufacturing of arsenic acid" lifecycle stage reported at 100-1000 t/y. The registration also includes the intermediate (precursor) use of arsenic acid at industrial sites, with the sector of use indicated as 'manufacture of basic metal, including alloys". This 2014 dossier is still the last registration dossier received by ECHA for arsenic acid (as of 10 December 2020).

It should be noted that the manufacturing lifecycle stage (including synthesis, transfer and storage steps) is not subject to the authorisation process. Furthermore, the manufacture of the substance may be possible for the uses exempted from authorisation (ECHA, 2015), and for the export.

B.2.2. Uses, including uses in articles

According to the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012), the main use (97 % of the uses) (Annex XV, ECHA 2011) in EU was as a fining agent in the manufacture of speciality glass for removing bubbles from the glass melt. This use of the substance appeared to be as "processing

agent", similar to the use of diarsenic trioxide As_2O_3 in glass making (Background document for As_2O_3 Annex XV, ECHA, 2010).

The addition of arsenic acid releases oxygen late in the fining process which made the bubbles more easily absorbed by the melt (Annex XV, ECHA 2011). Arsenic acid was used in the industrial Special Glass Sector, in particular in the manufacture of black and white ceramic glass. The available registration data indicated closed processes for the use in glass making (PROC 1 and PROC 3), but also included transfer processes (PROCs 8a and 8b) where the opportunity for exposure could arise. Although the registrations considered the use of the substance as an intermediate, this use of arsenic acid rather appeared to be as a "processing agent", similar to the use of diarsenic trioxide (As_2O_3) and diarsenic pentaoxide (As_2O_5) in glass making (Annex XV, ECHA, 2011).

According to the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012), the second known use of arsenic acid is in the production of copper foil for printed circuit boards (electronic components sector). In 2015, an authorisation has been applied for (and granted with Commission Implementing Decision of 7.6.2019, C(2019) 4134 final)[7] for this use. This AfA describes how the rolls of base foil, or drums foil, are processed through a sequence of chemical and electro-chemical processing steps. The final processes apply protective chemical conversion coatings that prevent corrosion to both surface of the foil during storage or lamination. Arsenic acid is used as adjuvant that prevents the formation of hydrogen during the electrochemical reactions. In the AfA, the technical function is as a surface agent and the tonnage is reported as 3.25 tonnes per year, all imported. As stated in the opinion by RAC and SEAC (RAC and SEAC, 2017), it is important to recognise that the final product, the copper foils, do not contain arsenic acid. Any arsenic acid is either included on a matrix (which has a key role in the electrolytic treatment of the copper foils) or precipitated in undefined arsenic forms by rinsing. The RAC and SEAC opinion described how the aqueous effluents are subject to on-site wastewater treatment before release to municipal sewer. RAC considers the RMMs to be generally appropriate and effective in limiting the risks to workers and the general population and no additional conditions for authorisation are proposed. This is also reflected in the Commission decision.

The condition of the authorisation related to the tonnage is that the amount of arsenic acid used by the authorisation holder in the authorised use does not exceed 1 tonne per year until 2020, 800 kg per year until 2022 and 700 kg per year until 2024. This authorisation has a review period which shall expire on 22 August 2024 and the latest submission date for the review report is 22 March 2023. It is important to note that the AfA has been submitted to allow enough time to phase out arsenic acid in this use and ECHA has been informed that the applicant does not intend to submit a further AfA after the review date.

The recycling or waste handling of articles where the specific substance is incorporated are not expected to cause exposure to humans (workers or indirectly exposed via the environment) as the concentrations of the substance are low as described in the authorisations.

The use information in two more recent registration dossiers (falling under the joint submission) were consistent with what was considered in the background document for arsenic acid in the context of ECHA's recommendation for the inclusion of substances in Annex XIV (ECHA, 2012).

[7] https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12449/term

A 2014 registration dossier also included the intermediate (precursor) use of arsenic acid at industrial sites, with the sector of use indicated as 'manufacture of basic metal, including alloys".

One downstream user report was also received in 2012, with use information also consistent with the joint submission use information.

To date no application for authorisation (AfA) has been received for the main use (glass making) reported above. It is assumed this is because this use has been phased out following inclusion of arsenic acid on the Authorisation List (Annex XIV), similar to that done for diarsenic trioxide and diarsenic pentaoxide (IT CA, 2017). To date no SiA notifications have been made under Article 7(2) for arsenic acid.

There is no information available about the potential import of articles into the EU containing arsenic acid above concentration of 0.1%, as ECHA has not received any SiA notifications.

B.2.3. Uses advised against by the registrants

There are no uses advised against in the registrations.

B.2.4. Description of targeting

This Annex XV, Article 69(2) report is targeted on the potential release of arsenic acid from articles and exposure to arsenic acid when used in articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substance was included in the Annex XIV, i.e. carcinogenicity. It is to be noted however, that according to article 56 of REACH, incorporation of an Annex XIV substance in articles falls under the authorisation procedure. This is further explained in the Q&A ID no 564 (see footnote 1).

B.3. Classification and labelling

Classification according to CLP

Arsenic acid

Carc. 1A H350; Acute Tox. 3 H331; Acute Tox. 3 H301; Aquatic Acute 1 H400; Aquatic Chronic 1 H410.

Classification according to the Classification and Labelling Inventory

There have been 14 notifications (in 4 aggregations) to the C&L inventory for arsenic acid. 4 of them reproducing the harmonised classification (above). 6 of them are deviating i.e. dropping the aquatic acute 1. 4 of the notifications add additional self-classifications i.e. Skin Corr. 1C, Eye Dam.1, Repr 2.

B.4. Environmental fate properties

Not relevant.

B.5. Human health hazard assessment

Arsenic acid was included in Annex XIV based on its carcinogenic properties (Carc. 1A). Other human health endpoints are not relevant for this dossier. In the context of applications for authorisations, RAC has established a reference dose response relationship for carcinogenicity of the 3 inorganic arsenic compounds diarsenic pentoxide, diarsenic trioxide and arsenic acid (RAC, 2013) in which the risk estimates were derived (see Table 2 below). In terms of

bioavailability, it is stated that “Data on the speciation of arsenic under different exposure conditions are inadequate to permit any differentiation, therefore the risk assessments below are considered to apply to all forms of inorganic arsenic, in the absence of data to the contrary”.

Table 2: Excess lifetime cancer risk

Population / route	Parameters	Excess lifetime lung cancer mortality risk	Excess lifetime risk of lung tumours
Workers	40 year working life (8h/day, 5d/week)	1.4 x 10^{-4} per µg As/m^3	
General population	70 years (24 h/day every day); 89-year life expectancy	1.0 x 10^{-3} per µg As/m^3	
Dermal exposure	$BMDL_{0.5}$ = 3 µg As/kg/day (0.5% excess risk of cancer)		1.7 x 10^5 per µg As/m^3 bw/day
Oral exposure (general population)	$BMDL_{0.5}$ = 3 µg As/kg/day (0.5% excess risk of cancer)		1.7 x 10^{-3} per µg As/kg bw/day

The opinion of the RAC on the evaluation of the occupational exposure limits (OELs) for arsenic acid and its inorganic salts (RAC, 2017) states that “Despite mechanistic indications of a threshold mode of action, the available data do not allow the identification of a threshold”.

In developing its opinion on the application for authorisation, RAC confirmed that it is not possible to determine a DNEL for the carcinogenic (category 1A) properties of the substance in accordance with Annex I of the REACH Regulation.

B.6. Human health hazard assessment of physicochemical properties

Not relevant.

B.7. Environmental hazard assessment

Not relevant.

B.8. PBT and vPvB assessment

Not relevant.

B.9. Exposure assessment

B.9.1. General discussion on releases and exposure

For this report only releases from articles and the exposure during the use of the substance in articles are relevant. When identified uses do not lead to arsenic acid being present in articles, there is no potential for releases or exposure from articles and no need for further assessment of that use.

It should be noted that, like for other inorganic salts of metals, any hazard would likely come from the metal ion (i.e. arsenic in this case) and if arsenic were to be found in articles (e.g. following analytical analysis as part of an enforcement campaign), it would be difficult for enforcement authorities to know whether this would be coming from arsenic acid or different arsenic salts.

The following uses have been reported for arsenic acid.

Production of glass

In the EU, arsenic acid was used in the industrial Special Glass Sector, in particular in the manufacture of black and white ceramic glass. The available registration data indicated closed processes for the use in glass making (PROC 1 and PROC 3), but also included transfer processes (PROCs 8a and 8b) where the opportunity for exposure could arise. However, based on the fact that no applications for authorisation have been received for this use of arsenic acid after the sunset date (22/08/2017) following its inclusion in Annex XIV (14/08/2014), there is no (legal) use in the EU and it is assumed that this use of the substance has been phased out in the EU. This is similar to the case of the substitution of diarsenic trioxide in glass (IT CA, 2017).

Production of copper foils in printed circuit boards

The rolls of base foil, or drums foil, are processed through a sequence of chemical and electro-chemical processing steps. The 'Releases' section (9.1.1.2) of the Chemical Safety Report (AfA, 2017) states "It is assumed that 99.9% of the substance [arsenic acid] is consumed during the scenario. About 30% are included as arsenic on a matrix (copper sheets), whereas about 70% precipitate in undefined arsenic forms (e.g. as arsenic oxide and arsenic hydroxide) and become part of a waste sludge". However, the RAC and SEAC opinion (RAC, SEAC, 2017) on this AfA states that "it is important to recognise that the final product, the copper foils, do not contain arsenic acid. Any arsenic acid is removed from the finished articles by rinsing".

ECHA has not investigated the exposure from the recycling or waste handling of articles where the specific substance is incorporated. However, these are not expected to cause exposure to humans (workers or humans indirectly exposed via the environment) or to the environment as the concentrations of the substance in articles are reported to be negligible or low (below 0.1%) as described in the authorisations.

B.9.1.1. Summary of the existing legal requirements

The use of arsenic in wood preservation is covered by entry 19 of annex XVII of REACH.

Arsenic acid is subject to the Prior Informed Consent (PIC) Regulation (649/2012) and is listed in Part 1 of Annex I are subject to the export notification procedure.

The use of arsenic compounds in pharmaceuticals is covered by Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC.

As a consequence of its classification as a carcinogen category 1A arsenic acid is covered by the following downstream legislation (Section 21 CLP Guidance Document, ECHA 2019);

- Chemical Agents Directive 98/24/EC and the Carcinogens and Mutagens Directive 2004/37/EC meaning that employers are obligated to minimize worker exposure to this substance as far as possible and must arrange for medical surveillance of workers exposed to these substances. There is also an EU occupational exposure limit (OEL) of 0.01 mg/m3 for arsenic acid;

- Commission Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food. Such materials and articles must not contain arsenic acid;

- Regulation (EU) 2017/745 on medical devices and Regulation 2017/746 on in vitro medical devices (to replace Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro Diagnostic Medical Devices from 2022). Under these new regulations, such devices must not contain arsenic acid;

- Regulation (EU) 528/2012) concerning the making available on the market and use of biocidal products. Arsenic acid meets the exclusion criteria;

- Regulation (EC) 1107/2009 on authorisation and marketing of pesticides. Arsenic acid meets the non-approval criteria;

- Regulation (EC) 1223/2009 on cosmetic products. The use of arsenic acid in such products is prohibited. Arsenic acid meets the non-approval criteria;

- Regulation (EC) 66/2010 on the EU Ecolabel. An ecolabel will not be awarded to goods containing arsenic acid;

- Commission Decision (EU) 2016/1332 establishing the ecological criteria for the award of the EU ecolabel for furniture:

    - Paints, primers or varnishes used on wood or wood-based materials shall not contain substances based on arsenic (and other heavy metals cadmium, lead, chromium (VI), mercury and selenium) at concentration exceeding 0.01% w/w for each individual metal in the in-can paint, primer or varnish formulation.
    - Chemical testing requirement limit of ≤ 1.0 mg/kg for arsenic in leather, textiles and coated fabric covering material. Different limits for chromium, cobalt, lead, nickel, antimony, cadmium, copper and mercury.
    - Pigments in dyeing and printing processes based on arsenic (and cadmium, lead, chromium VI, mercury, and antimony) shall not be used.

- Directive 2009/48/EC on the safety of toys. As a consequence of its harmonised classification as a carcinogen category 1A, arsenic acid is restricted in toys if certain conditions. Recital 22 states that limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practise will be present.

  The following migration limits of **arsenic** from toys or components of toys, shall not be exceeded:

Element	**mg/kg in dry, brittle, powder-like or pliable toy material**	**mg/kg in liquid or sticky toy material**	**mg/kg in scraped-off toy material**
Arsenic	3,8	0,9	47

Under REACH, arsenic acid was proposed for SVHC listing by Norway on 01/08/2011, the substance was listed in the candidate list 19/12/2011 (ECHA 2011) and included into Annex XIV in 2014 (EC 2014).

REACH has several requirements for substances on the candidate list including notification of its presence in articles if >0.1% and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article contains more than 0.1% by weight of arsenic acid (Article 33(b)).

The entries in Annex XIV for arsenic acid authorisation set a last application date of 22/02/2016 and a sunset date of 22/08/2017.

Arsenic acid, as a substance or in a mixture, is restricted with entry 28 of Annex XVII in REACH (placing on the market for supply to the general public), being placed on the Appendix 1.

Information on existing legislations in European Union relevant for arsenic acid is available on ECHA's website under EU Chemicals Legislation Finder (EUCLEF): https://echa.europa.eu/fi/legislation-obligation/-/obligations/100.029.001 .

B.10. Risk characterisation

Not relevant - there is no use of these substances that would lead to a non-adequately controlled risk from arsenic acid concentrations in articles that are not already regulated under REACH Authorisation.

C. Available information on alternatives

For the authorised use of arsenic acid in the production of copper foil for printed circuit boards, the RAC and SEAC opinion (RAC & SEAC, 2017) on the AFA mentioned above reports:

"The applicant states that the company has been working for the past 10 years on developing a production process that is free of arsenic acid. The applicant provided a report on the testing of several potential alternatives under different test conditions (including temperature, density, copper concentration and chloride concentration). They have carried out literature reviews and laboratory tests in order to find a promising substitute. Based on this work they identified candidates for substitution that were taken forward in the semi-industrial tests. This R&D work resulted in the identification of a suitable alternative, the identity of which is claimed confidential, while the final test report is available in French and is confidential as well. For this reason, the term "alternative (A)" is used in this opinion when referring to the arsenic acid-free alternative.

Over the past five years the applicant has industrialised alternative (A). Currently, about 30% of the copper foil production of the applicant is arsenic acid free, and copper foils for new products are systematically manufactured without the use of arsenic acid. The applicant has shown that they have implemented a flexible production line for both arsenic acid and arsenic acid free manufacture. According to the substitution schedule provided by the applicant all copper foil will be produced without the use of arsenic acid by 2030. The applicant has informed its customers that, after 2030, it will no longer sell copper foils produced with arsenic acid. The timeline for this remaining substitution has been documented in the application (AoA, 2015).

This AfA has been submitted to allow sufficient time to phase out arsenic acid in this use and ECHA has been informed that the applicant does not intend to submit a further AfA after the review date of (21/02/2023)."

D. Justification for action on a Community-wide basis

Not relevant, as no restriction is proposed at present.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

Not relevant, as no restriction is proposed at present.

F. Socio-economic Assessment of proposed restriction

Not relevant, as no restriction is proposed at present.

G. Stakeholder consultation

The Annex XV report was subject to a Call for evidence from xxx [2021] to xx xxx [2021] (6 weeks). [To be updated following CfE.]

H. Other information

Not relevant.

References

SVHC identification

ECHA (2011) Member State Committee support document for identification of arsenic acid as a substance of very high concern available at https://echa.europa.eu/documents/10162/bc77d03b-2f02-4084-8fab-2b8d586f342a

Recommendation for the inclusion of substances in Annex XIV

ECHA (2010) Background document for diarsenic trioxide - document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV available at: https://echa.europa.eu/documents/10162/46eb55f6-b2ba-43e6-ad28-3064b89e93a5

ECHA (2012) Background document for arsenic acid - document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV available at: https://echa.europa.eu/documents/10162/3eabf798-7459-4ef5-a2c3-5e1e0f3f4f52

Applications for authorisation

RAC (2013) Application for authorisation: establishing a reference dose response relationship for carcinogenicity of inorganic arsenic compounds available at: https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_as_en.pdf/57b6e1ba-51b6-4fbf-b9c5-ca3ba952dd9f

ECHA (2015) Generic exemptions from the authorisation requirement available at: https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf

AfA (2015) The application for authorisation received by ECHA on arsenic acid are available at https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/12449/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=231-901-9&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

AoA (2015) Analysis of alternatives available at: https://echa.europa.eu/documents/10162/6e3e0878-4bd9-4d34-952a-5370a4d09d02

RAC & SEAC (2017) Consolidated version of RAC and SEAC opinion on the application for authorisation for industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Boards is available here: https://echa.europa.eu/documents/10162/a93efe3c-bf63-729b-bb93-1aff96d3e02a

IT CA (2017) Substitution of diarsenic trioxide in Murano glass" presentation available at:https://echa.europa.eu/documents/10162/23551137/maria_letizia_polci_en.pdf/f927879f-bf38-0343-387e-06474a93f21d]

Authorisation

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