17 December 2010

Background document for Diarsenic trioxide

Document developed in the context of ECHA's second Recommendation for the inclusion of substances in Annex XIV

1. Identity of the substance

Chemical name:	Diarsenic trioxide
EC Number:	215-481-4
CAS Number:	1327-53-3
IUPAC Name:	Dioxodiarsoxane

2. Background information

2.1. Intrinsic properties

Diarsenic trioxide was identified as a Substance of Very High Concern (SVHC) according to Article 57(a) as it is classified according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as a carcinogen, category 1[1], R45 (may cause cancer) and was therefore included in the candidate list for authorisation on 28 October 2008, following ECHA's decision ED/67/2008.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

According to information provided during the public consultation on the recommendation to include diarsenic trioxide in Annex XIV, industry (the REACH Arsenic and Arsenic Compounds Consortium managed by the German association Wirtschaftsvereinigung Metalle (WVM; RCOM 2010)) provided new information on volumes of As_2O_3 on the European market and its uses, which substantially differ from the information collected in a study by RPA (2009) that, so far, was used in this report.
The new data by WVM provide an estimate over the last 3 years and are summarised in Table 1. The As-Consortium gathered up to date information from its members and derived a generic mass flow for As_2O_3 in the EU (Table 1). While this mass flow may

[1] This corresponds to a classification as carcinogen 1A, H350 (may cause cancer) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (List of harmonised classification and labelling of hazardous substances)

not be entirely exact due to uncertainties related to direct imports from outside the EU by downstream user sectors, it can be considered that the reported uses and relative quantities consumed in these uses are indicative for the EU market as of today (WVM; RCOM 2010).

Table 1: Manufacturing and use mass flow of As_2O_3 in the EU

Manufacturing	**t/y**		**Use in the EU**	**t/y**
Manufacturing	1500		As ultra pure	30-40
Manufacturing of impure form	320		Chemicals	60
Import	500-600		Zinc production	500-600
			Glass	100-150
			Total use in EU	***690-850***
Total	**~2400**		**Export to outside EU**	**t/y**
Disposal as waste	*-200*		As CCA	70-100
			As As_2O_3	1100-1200
			Total exported	***~1200-1300***
Net total placed on market	***2200***		**Total**	**~1900-2150**

Most As_2O_3 is produced as a by-product from the copper primary materials smelting and refining (and to a smaller extent from lead production). This means that the manufacture of As_2O_3 depends largely on the production volume of these metals and the arsenic impurity levels in the ores, which can vary quite considerably.

The volume placed on the market further depends on the consumer demand. More As_2O_3 is disposed of as toxic waste in safe and controlled conditions in periods of low demand while more material for the market may be manufactured for different use applications when the demand (e.g. in the zinc sector) is higher.

Diarsenic trioxide manufacturing volumes within the EU are estimated at 1,820 t/y. Amounts imported are in the range of 500 – 600 t/y and those disposed of are around 200 t/y. This results in a total volume placed on the global market of 2,200 t/y. The largest part of this volume (1,100-1,200 t/y) is exported outside the EU in form of As_2O_3 and a smaller part (70-100 t/y) in form of the wood-preservative Copper-Chromium-Arsenic (CCA). The volume used within the EU is in the range of 690 – 850 t/y (thereof uses in the scope of authorisation 600 – 750 t/y).

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

The number of manufacturers of As_2O_3 in the EU is limited to 2 responsible for a production of approximately 1,820 tons, mostly but not exclusively in the pure form (Table 1). Part of this material is disposed of in safe and strictly controlled disposal conditions (WVM, RCOM 2010). The emissions of arsenic to the environment for these 2 manufacturers are listed in Table 2.

The number of importers known to the As-Consortium is very limited and accounting for approximately 500-600 t of imported As_2O_3. Most imported material is used in the zinc sector.

Table 2: Environmental emissions of As_2O_3 manufacturers in the EU [2009]

Manufacturer	**Water emissions** (kg arsenic/year)	**Air emissions** (kg arsenic/year)
1)	35 kg	2.7 kg (stack emissions)
2)	28.9 kg	604kg

source: http://prtr.ec.europa.eu/PollutantReleases.aspx

The water emission ratio for manufacturer (1) is in the order of 20-25 g per tonne As_2O_3 produced and the air emission ratio is 1-2 g/t produced. For manufacturer (2) the ratios are in the order of 70-90 g/t (to water) and 150-170 g/t (to air). In general it can be concluded that emissions resulting from the production of As_2O_3 are relatively independent from the volume produced (given they are related to the elimination of As as an impurity from Lead and Copper) and much lower than general emissions from diffuse sources like power stations, steel industry and others (e.g. E-PRTR and national emission inventories - European Pollutant Release and Transfer Register (http://prtr.ec.europa.eu/PollutantReleases.aspx) (WVM; RCOM 2010).

2.2.2.2. Uses and releases from uses

The main uses of diarsenic trioxide seem to be in the manufacture of zinc by electrolysis, in glass and for manufacturing other chemicals and ultra-pure arsenic metal. Some uses are declining rapidly due to regulatory initiatives in the EU. For example, the use of CCA (Copper-Chromium-Arsenic) as a wood preservative is in essence phased out in the EU due to specific restrictions on marketing and use of this agent while also remaining export declines, resulting in limited production and closures (WVM; RCOM 2010).

Description of uses

1. Wood preservation

Copper-Chromium-Arsenic based wood preservatives were in the past a major use for As_2O_3. The restriction on its use in the EU has led to a decreasing production in the EU, which recently is is for export only. In 2009, manufacture declined to less than 100 tons (from a couple of thousand tons a decade ago) and the As-Consortium was informed that the last remaining production plant decided to stop production before the first Registration deadline of December 2010, thereby eliminating the application and manufacturing of diarsenic trioxide for this use in the EU (WVM; RCOM 2010).

It should be noted that the use of arsenic compounds in wood protection products falls under the scope of the Biocides Directive (See section 7). Use in biocidal products within the scope of Directive 98/8/EC {Art. 56(4b)} is exempted from authorisation.

2. Paints, Varnishes etc.

Diarsenic trioxide is used in small quantities in vitrifiable enamels. These types of materials have common properties with glass (and alloys) in that due to the matrix effect, the hazard properties of the enamel are clearly different from the constituting

compounds. The Consortium has neither detailed information on how As_2O_3 is used for the production of vitrified enamels, nor if this is done under strictly controlled conditions (WVM; RCOM 2010).

According to claims in the comments received (WVM, RCOM 2010), the arsenic containing enamels are used as an isolated intermediate under strictly controlled conditions. This could however not be checked as no process description of this use was submitted to ECHA.

3. Pharmaceutical Preparations

The use of arsenic compounds in (Western) medicines progressively tailed off during the latter part of the 20th century and had disappeared by the mid-1990s. However, the use of arsenic (as injected diarsenic trioxide) has reappeared following extensive studies in China. No quantitative data are available but it is important to stress that the use of arsenic compounds in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)} is exempted from authorisation (RPA, 2009).

It is further confirmed that EU manufacturers do not produce diarsenic trioxide for the purpose of preparing pharmaceuticals (MVM; RCOM 2010).

4. Glass and Glass Products

Diarsenic trioxide is used for the manufacture of special glass and crystal where it acts as a decolourisation agent, enamel or a fining[2] agent (WVM; RCOM 2010). It may further be used as an opacifying agent[3].

The special glass sector produces around 6% of the glass industry output, and in terms of tonnage it is the fourth largest sector. Special glass products have a relatively high value and represent an extremely broad sector covering a wide range of products. The main products are: lighting glass (tubes and bulbs), optical glass, laboratory and technical glassware, borosilicate and ceramic glasses (cookware and high temperature domestic applications), and glass for the electronics industry (LCD panels). Until recently, the product list would have included cathode ray tube (CRT) glass for televisions and monitors. However, there has been a dramatic shift to LCD screens in recent years and CRT glass is no longer made in the EU (RPA, 2009).

Overall, the estimate for EU usage of diarsenic trioxide in glass manufacture is 150 t/y (WVM; RCOM 2010), most of which is used for the production of special glass. The glass industry considers manufacture of arsenic containing glass as carried out under closed conditions (WVM; RCOM 2010).

Industry (CPIV and WVM; RCOM 2010) considers all raw materials used in the melting phase of the glass as isolated intermediates for the production of a new substance, i.e. glass. In their opinion, this applies equally to As_2O_3 as the oxide is completely and immediately transferred to a non-crystalline or vitreous inorganic macromolecular structure by the high temperature of the melt, thereby completely changing its chemical speciation and properties.

[2] "Fining" means removing of gas bubbles from the glass melt.

[3] Diarsenic trioxide may be used to make glass and enamels opaque.

However, according to the information provided by industry, arsenic trioxide is used as a decolourising, opacifying and fining agent. These uses do not seem to be uses of the substance as intermediate in accordance with the agreed definitions (Definition of intermediates, 2010):

> *An intermediate 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.*

Diarsenic trioxide is not used in the synthesis of glass itself but as processing agent for modifying the properties of glass (degassing, decolourisation, etc.), it consequently cannot be considered as an intermediate in the sense of the above definition.

5. Manufacture of zinc metal

A main use of diarsenic trioxide with an estimated volume of 500-600 t/y is the industrial use in the manufacture of zinc metal by electrolysis. As_2O_3 is added to the zinc solution to precipitate metal impurities such as copper, cobalt, nickel and iron from the solution. A small amount of the diarsenic trioxide forms however the very toxic arsine (AsH_3), requiring maximal security to prevent any exposure. The arsine is removed from the off gas with an oxidative scrubber. Overall, the process is conducted in closed and continuous conditions with occasional controlled exposure (PROC 2) (WVM; RCOM 2010).

Industry (WVM; RCOM 2010) is claiming that the use of As_2O_3 in the manufacture of zinc metal by electrolysis would be a use of As_2O_3 as a transported isolated intermediate. However, on the basis of the process descriptions provided by WVM / Eurometaux (RCOM 2010), this interpretation appears questionable (Definition of intermediates, 2010):

> *The electrolytic zinc production requires purification of the starting material as the zinc electrolysis is extremely sensitive to impurities in the electrolyte. In particular impurities / elements with electrode potential between Zn^{2+} and H^+ or those which are more electropositive have to be removed before electrolysis. Therefore one purification step is the treatment with arsenic trioxide solution. Arsenic trioxide is either directly solved in water or in sodium hydroxide to generate a solution. This solution is applied to zinc sulphate solution and the metal contaminants are removed by precipitation with arsenic trioxide solution.*

Therefore arsenic trioxide is rather used as a purification / processing agent than a reactant for manufacturing another substance with the consequence that arsenic trioxide is not an intermediate in this process.

The different steps of the application of arsenic trioxide can be summarised as follows:

1. *Dissolving of arsenic trioxide: making of ionic mixtures is exempted from registration according to the guidance for Annex V*
2. *Precipitation of impurity elements: the products generated by precipitating them with diarsenic trioxide are not themselves manufactured but result form a chemical reaction that occurs during the end use of another substance. These precipitates might be regarded as by-products. They are exempted from the registration obligation if they fulfil the criteria laid down in entry 5 of the guidance for Annex V*

In summary, the application of diarsenic trioxide in electrolytic zinc manufacture needs to be regarded as an end use rather than as intermediate use because arsenic trioxide acts as a purification / precipitation agent for removing interfering elements.

6. Alloys
Uses of arsenic for producing alloys are actually all based on arsenic metal (WVM, RCOM 2010).

7. Electronic Components
The applications in the EU for (a) the production of ultrapure Gallium Arsenide, (b) Arsenic as a dopant, and (c) Selenium based alloys are all applications of arsenic metal (WVM, RCOM 2010).

Releases from uses

Releases of diarsenic trioxide or arsenic compounds during the uses described above will tend to be associated with processing. As such, releases will rather occur under controlled working conditions. Further information on the two major uses – glass and zinc metal manufacture by electrolysis - is presented below.

Glass Processing
The use of arsenic in the glass industry has long been recognised as requiring care for both the health of the workers and the surrounding environment. Although major glass production facilities within the EU do use significant quantities of arsenic, their emissions to the environment are less than for many other facilities (such as power stations and major steel works[4]). Nevertheless, there are several glass manufacturing facilities (across the EU) each with arsenic emissions in the range 0.1 to 0.7 t/y (RPA, 2009).

More generally, glass manufacture is covered by IPPC[5] resulting in a requirement to reduce emissions to the environment. This, in turn, led to the development of an *IPPC*

[4] By inspection of the European Pollutant Emission Register (eper.eea.europa.eu/eper/default.asp)
[5] Most recently codified as: Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control, OJ L24, 29.01.02008, pp 8-29.

Reference Document on Best Available Techniques[6] in 2001 which is now being updated (EC, 2008), with references to (di)arsenic trioxide.

According to information provided by WVM (RCOM, 2010), the glass sector applies in general strict exposure restriction conditions as it uses several materials with potential CMR properties. As_2O_3 is delivered in tank container trucks, big bags or drums for the smaller mainly artisan companies. In the industrial glass sector material is pumped hydro pneumatically or under closed conditions into closed silos and transported on covered conveyor belts to the furnace. Air releases from the conveyer belts are treated by bag filters and the filtered dust is returned as recycled material onto the conveyor belts. Smaller quantities are handled with big bags or even polyethylene bag lined drums. With respect to the high toxicity of the material in industrial facilities they are emptied and handled under strictly controlled conditions (SCC). However, it is well recognized that different from the industrial glass sector, SCC is not guaranteed for the artisan handmade glass sector where supply of the material and mixing often occur under suboptimal conditions..

Information provided by the Italian Competent Authority indicates problems with preventing occupational exposure in the manufacturing of hand-made decorative glass for arts and crafts. Biological monitoring of workers in glass manufactories in the Murano district of Venice, carried out through urinary arsenic measurement, revealed that workers employed in the mixture preparation and in the furnace work are still significantly exposed to arsenic despite the technical preventive measures adopted (mean concentrations of different As species in urine samples of workers are 2-3 times higher than the upper limit of reference for the non-exposed population (Montagnani et al., 2006)). Main problems are apparently the dustiness of As_2O_3, which is mixed with the other glass raw materials in form of fine powder, and the high volatility of As_2O_3 at its sublimation temperature (at least 20% loss of the As added), which lead to inhalative exposure. About 80 manufactories with ca. 800 – 1000 workers are manufacturing arsenic containing art glass. The annual consumption of As_2O_3 for art glass manufacture is 8.2 t in the Murano district (estimate for entire Italy 12 t/yr).

There are several further epidemiological studies conducted in the Murano glass district which confirmed a significantly increased SMR for lung cancer. While As_2O_3 was not specifically identified as the main cause for this disease, it can be assumed that the substance partly contributed to this enhanced risk in the artisan glass sector. The As-Consortium tried to find confirmation if practices in the artisan handmade glass making would lead to As_2O_3 exposure in other areas but could not find confirmation of such. On the contrary, artisan glass productions in countries like Austria or Belgium seem either to use other substances for the fining and decolourisation in these types of crystal or have better controlled exposure management (WVM, RCOM 2010).

The situation in the Murano region may have improved in the last years, as biomonitoring data on arsenic exposure of glass makers between 1996 and 2006 suggest. These data collected by the Stazione Sperimentale del Vetro (SSV) suggest that arsenic exposure of workers manufacturing arsenic containing glass or making

[6] Sometimes referred to as a BREF.

articles of it may have decreased between 1996 and 2006 by roughly two thirds to approximately 5-7 µg As /g creatinine, which is below the Italian limit value (Eurometaux, SSV, RCOM 2010).

Many items of special glass may be collected and, possibly, recycled. However, the collection and physical sorting of different glasses is unlikely to lead to significant exposures to arsenic (at least within the EU) (RPA, 2009).

Manufacture of zinc metal

Diarsenic trioxide is claimed to be used under "strictly controlled conditions" (WVM & Eurometaux, RCOM 2010) in the zinc manufacturing process to ensure worker safety. According to the process descriptions received, the As_2O_3 is delivered in tightly closed drums, which are automatically opened and emptied under completely closed cover and low-pressure in order to dissolve the As_2O_3, which is used in solution guaranteeing minimal emissions and optimal protection of the workers. All handling of As_2O_3 is carried out by trained personal wearing appropriate protection equipment. The transport of solutions to the various reaction vessels is through pipes. These vessels are connected to a suction system keeping them at slight under-pressure in order to remove and filter out arsine or As-containing aerosols. Arsenic concentrations at the workplaces are monitored and workers are supervised by occupational physicians. As-containing waste (if any) is disposed of at sites certified for this kind of hazardous material.

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) the supply chain

As already mentioned in section 2.2.2.1, manufacture of diarsenic trioxide takes place at 2 sites in the EU. In addition, as indicated under section 2.2.2.2, widespread geographical distribution can be assumed for uses in the glass industry whereas uses in the zinc industry seem to be limited to a very small number of sites.

Based on the information provided, it can be concluded that:

1) the supply chain of this substance includes only few levels (from the manufacturer/importer to the last actor affected by a possible authorisation decision).

2) the supply chain seems to comprise two types of industry branches and these are well organised in effective industry associations (glass industry, metal industry).

Therefore, it can be concluded that the supply chain for diarsenic trioxide is of rather low complexity: the substance is manufactured, imported, used as intermediate (for manufacture of pure As and As-chemicals) and further used for the manufacture of glass and zinc (see above).

2.3. Availability of information on alternatives[7]

Use in Enamels and Glass Processing

Fining Agents
Diarsenic trioxide is used as a fining agent. The industry has indicated (CPIV, 2008) that arsenic acid may also be used for this purpose - albeit under different processing conditions (CPIV, 2009). Due to concerns about the its use of As_2O_3, there are various established alternative substances including:

- sodium sulphate (used in lead crystal);
- antimony trioxide (used in lead crystal);
- sodium/potassium nitrates with antimony trioxides (used in special glasses); and
- cerium oxide.

Decolourising Agents
Diarsenic trioxide is used as decolourising and opacifying agent in glass and enamels. The industry has indicated (CPIV, 2008) that arsenic acid may also be used for this purpose - albeit under different processing conditions (CPIV, 2009). As with the fining agents, there are various established alternative non-arsenic substances including:

- antimony trioxide (decolourising agent for glass and an opacifier in ceramics and enamels);
- selenium (particularly in lead crystal); and
- cerium oxide (in special glass and as an opacifier in enamels/ceramics).

Arsenic-Free Glass
Although in certain crystal applications As_2O_3 can be replaced by PbO (Lead oxide), the use of diarsenic trioxide in *special industrial glass* remains so far essential (WVM, RCOM 2010). The Italian government is well aware and concerned about the situation in the artisan glass sector and reconfirmed recently that they are progressing well with the development of alternatives to the application of As_2O_3 in artisan glass/crystal. Several other less harmful salts (including phosphor and sulfur based) are under investigation and a report on the substitutability of As_2O_3 is expected later in 2011.

It should be noted that several major glass producers and computer companies are now promoting the use of arsenic-free glass in computer monitors (RPA, 2009).

Given the range and diversity of alternatives to the use of diarsenic trioxide, it might be expected that alternatives would be available with suitable technical and economic characteristics for most applications. Although it is accepted that there are alternatives for most domestic (lead crystal) applications, the glass industry (CPIV, 2008) has

[7] Please note that this information was not used for the prioritisation.

highlighted a number of applications where there are technical difficulties in replacing arsenic in special glass:

- pharmaceutical packaging glass which would require further investigation into the suitability of any alternative materials;
- although some glass-ceramic hobs (cooker tops) are now arsenic-free, producing clear glass hobs remains a difficult challenge;
- some optical filter glass relies on the intrinsic properties (i.e. optical wavelengths) of arsenic for which there are no alternatives; and
- use of alkali-free glass in opto-electronic applications.

Many of the alternatives to the use of arsenic in glass/enamel processing may be considered potentially harmful to human health and the environment. By way of example, antimony trioxide is the subject of an (as yet unpublished) EU Risk Assessment Report under the Existing Substances Regulation[8]. However, such potential effects are taken into account in developing appropriate operational practices.

2.4. Existing specific Community legislation relevant for possible exemption

Wood Preservative (CCA)
Especially the use of arsenic treated wood has been extensively covered by other regulations. Although initially it was considered suitable for general indoor and outdoor use, increasing concerns over its use led to a series of regulatory actions including:

Directive 89/677/EEC (amending for the eighth time Directive 76/769/EEC on Marketing and Use restrictions) stipulated that arsenic compounds may not be used as substances and constituents of preparations intended for use in the preservation of wood unless solutions of inorganic salts of the CCA type were used in industrial installations using vacuum or pressure to impregnate wood.

Several years later, **Directive 2003/2/EC** (adapting Directive 76/769/EEC to technical progress for the tenth time) restricted the use of CCA-treated timber to a limited number of end uses where structural integrity is required for human or livestock safety and skin contact by the general public is unlikely. This had to be implemented by 30th June 2004. These limited end uses account for a small proportion of the requirement for treated timber.

Another issue of importance to the evolution of the EU markets for wood treatment formulations is the **Biocidal Products Directive (98/8/EC)**. Arsenic pentaoxide was notified by industry as an active substance following the provisions of the Directive; however, a dossier was not submitted. This effectively prevents the use of arsenic in wood preservatives in the EU (but see points on imports below).

[8] European Chemical Substances Information System: Diantimony Trioxide (CAS 1309-64-4).

Directive 2006/139/EC (adapting Directive 76/769/EEC to technical progress), prescribes that arsenic shall not be used in the preservation of wood. Under Point 20 of Annex 1 to Directive 76/769/EEC as amended by Directive 2006/139/EC, CCA type C cannot be used to treat wood in the EU due to the fact that it has not been authorised under Directive 98/8/EC. A request for authorisation could, however, be made in the future in line with the requirements of Directive 98/8/EC (EC, 2008).

Pharmaceuticals. The use of arsenic compounds in medicinal products for human or veterinary use is regulated within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)} and is exempt from authorisation.

2.5. Any other relevant information (e.g. for priority setting)

No data available.

3. Conclusions and justification

3.1. Prioritisation

The total estimated volume of As_2O_3 manufactured in the EU is around 1820 t/y. The volume assigned to uses in the scope of authorisation is approximately 600 - 750 t/y.

Main use of the substance with a volume of 500 – 600 t/y seems to be for removing copper and cobalt impurities from zinc electrolyte solution in the process of zinc manufacture by electrolysis.

Diarsenic trioxide is claimed to be used under “strictly controlled conditions” (WVM & Eurometaux, RCOM 2010) in the zinc manufacturing process to ensure worker safety. All handling of As_2O_3 is carried out by trained personal wearing appropriate protection equipment. The transport of solutions to the various reaction vessels is through pipes. Vessels are kept at slight under-pressure in order to remove and filter out arsine or As-containing aerosols. Arsenic concentrations at workplaces are monitored and workers are medically supervised. As-containing waste (if any) is disposed of at sites certified for this kind of hazardous material.

The estimate for EU usage of diarsenic trioxide in glass manufacture is 150 t/y, with some uncertainty regarding imported quantities for this use.

The glass sector applies in general strict exposure restriction conditions as it uses several materials with CMR properties (WVM, RCOM 2010). According to industry, due to the high toxicity of As_2O_3, the material is handled in industrial facilities under strictly controlled conditions (SCC).

As regards occupational exposure, there seem to be problems with preventing such exposure in the manufacturing of hand-made decorative glass for arts and crafts (Montagnani et al., 2006). Several other studies indicate exposure to As and higher lung cancer frequencies in the Murano glass district, too. However, there is also a

study indicating that exposure to As may have decreased between 1996 and 2006 and may now be below the Italian occupational exposure limits. In the Murano region, about 80 manufactories with ca. 800 – 1,000 workers are manufacturing As-containing art glass. The annual consumption of As_2O_3 for art glass manufacture is 8.2 t in the Murano district (estimate for entire Italy 12 t/yr).

Although the use of arsenic containing glass can be considered widespread, based upon available information, it is assumed that the release of arsenic compounds from glass matrices/articles is most probably (very) low and hence not wide dispersive.

Verbal-argumentative approach

The volumes of diarsenic trioxide supplied to non-intermediate uses are relatively high (approximately 600 – 750 t/y). Consumer exposure via articles resulting from these uses can be considered insignificant and exposure of humans via the environment as controlled.

As regards occupational exposure there appear to exist problems with exposure control in (parts of the glass industry), in particular in manufactories for small scale manufacture of art glass. Extrapolation of the data from Italy regarding numbers of factories and workers involved would suggest that a considerable number of workers could be exposed and that the use of As_2O_3 for art glass manufacture should be considered as wide-dispersive.

On the basis of the prioritisation criteria, diarsenic trioxide can be considered as a candidate for prioritisation although there is some uncertainty about the extent of the problem of insufficient exposure control for workers in the glass industry.

Scoring approach

Score			Total Score
Inherent properties (IP)	Volume (V)	Uses - wide dispersiveness (WDU)	(= IP + V + WDU)
1 (Carcinogen, cat. 1)	5 (Relatively high volume)	Overall score: 3 * 3 = 9 Site-#: 3 (Use at a high # of sites) Release: 3 (significant exposure in (parts of) the glass industry)	15

Conclusion, taking regulatory effectiveness considerations into account

On the basis of the prioritisation criteria, diarsenic trioxide can be considered as a candidate for prioritisation.

If diarsenic trioxide is included in Annex XIV it should be considered to also include similar substances (e.g. As_2O_5) in order to prevent evasion of the authorisation requirement by replacing As_2O_3 with other arsenic compounds with a similar hazard potential.

4. References

COWI (2004): Advantages and Drawbacks of Restricting the Marketing and Use of Lead in Ammunition, Fishing Sinkers and Candle Wicks, Final Report prepared for DG Enterprise, dated November 2004.

CIC (2008): Lead Shot: Significant New Developments with Relevance to all Hunters, International Council for Game and Wildlife Conservation news item dated February 2008: www.cic-wildlife.org/index.php?id=324.

CPIV (2008): CPIV Answer to the Questionnaire of Arsenic Uses in the Glass Industry, detailed response to RPA consultation, dated October 2008.

EC (2008): Draft Reference Document on Best Available Techniques in the Glass Manufacturing Industry, Draft of February 2008 (updating the previous BREF dated December 2001), available from: http://ec.europa.eu/environment/ippc/brefs/gls_d1_0208.pdf

CPIV (2009): Responses to additional RPA questions, dated January 2009.

Definition of intermediates, 2010: Definition of intermediates as agreed by Commission, Member States and ECHA on May 4 2010. http://guidance.echa.europa.eu/docs/guidance_document/clarificationintermediates_201005_en.pdf

Montagnani, R, M Campagna, S Gasparello, A Hreiglich, P Apostoli (2006): L'esposizione ad arsenico nella produzione artigianale della bacchetta di vetro. Risultati del monitoraggio biologico e indicazioni preventive. G Ital Med Lav Erg 2006; 28:2, 158-162.

RCOM, 2010: RESPONSES TO COMMENTS DOCUMENT (RCOM) FOR DIARSENIC TRIOXIDE (EC NUMBER: 215-481-4)

RPA (2009): Data on manufacture, import, export, uses and releases of: diarsenic trioxide (CAS no: 1327-53-5); diarsenic pentaoxide (CAS no: 1303-28-2); lead hydrogen arsenate (CAS no: 7784-40-9); and triethyl arsenate (CAS no: 15606-95-8), as well as information on potential alternatives to their use. Report prepared for ECHA.