Association of the Glass and Ceramic Industry of the Czech Republic

EUROPEAN DOMESTIC GLASS

esga European Special Glass Association

INTERNATIONAL CRYSTAL FEDERATION

Description of the use of Lead oxides as intermediates in the manufacture of Lead Special Glass and Lead Crystal Glass

European Special Glass Association
European Domestic Glass
International Crystal Federation
Association of the Glass and Ceramic Industry of the Czech Republic

REACH AUTHORIZATION EXEMPTION REQUEST

INTERMEDIATE STATUS IN LEAD GLASS PRODUCTION

EXECUTIVE SUMMARY

The aim of the present document is to provide technical information with regard to the use of Lead Oxides in the production of Lead Special Glass and Lead Crystal glass and their “intermediate” status under EU REACH Regulation (1907/2006/EC).

Lead Glass is a UVCB substance under the REACH Regulation[1]. Indeed, the UK REACH Competent Authority underlined that “glass is considered to refer to those materials commonly called glasses”[2].

Exemption as transported isolated intermediate, in the glass production

Lead oxides that are used in the manufacture of lead glass meet the definition of intermediates inasmuch as they are

- transformed into a new substance, namely glass. A recent ECHA document is reaffirming that “the manufacture of a substance is not subject to the authorisation requirement”.[3]
- transported isolated intermediates, since they are produced elsewhere and transformed at the glass manufacturers’ site.

This is consistent with the ECHA document on “Clarification of the concept of intermediates under REACH”[4].

Exemption for food contact material applications (Art. 56(5)

Certain lead crystal glassware are used for food contact materials applications and as such comply with Art. 56(5) on substances classified as hazardous to human health used for food contact materials (Reg. 1935/2004). These applications are therefore out of the scope of authorization.

Exemption when risk is properly controlled (Art 58(2)

Article 58(2) of REACH allows to exempt from the authorisation requirement uses or categories of uses ‘*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*’.

A list of existing Community legislation is proposed to be considered for granting an exemption to the use of lead oxide and lead tetraoxide in the manufacture of glass (see point 8), as

- Existing EU legislation already addresses the glass manufacturing
- The existing legislation provide binding and enforceable minimum requirements for the control of risks from industrial use of lead monoxide and lead tetraoxide in glass

[1] REACH Regulation, Annex V, Entry 11
[2] UK REACH Competent Authority Information Leaflet Number 8 – Exemptions, in *www.hse.gov.uk/**reach**/resources/exemptions.pdf*
[3] CA/103/204 Q&A on the scope of certain authorization exempting provisions, 7 November 2014
[4] CA/04/2010 Clarification of the concept of intermediates, February 2010 and April 2010

manufacturing. In having a binding occupational exposure and biological limit for lead, supported by additional measures such as medical surveillance, Council Directive 98/24/EC ensures that harmonized, EU wide standards operate.

CONCLUSION

Lead oxide and lead tetraoxide are used as transported isolated intermediates (in the meaning of Article 3(15) REACH) in the manufacture of the substance lead glass. This use should therefore not be subject to authorization.

Raw materials that are used in the manufacture of glass meet the definition of intermediates inasmuch as they are transformed into a new substance, namely glass. They are transported isolated intermediates, since they are produced elsewhere and transformed at the glass manufacturers' site; this is consistent with the ECHA document on "Clarification of the concept of intermediates under REACH". Glass prepared from the set of different raw materials will exhibit its own properties that are different from the properties of the individual raw materials from which the glass has been synthesized.

We also remind that food contact materials applications are specifically out the scope of authorization (Art 56(5). Finally, ROHS applications for which an exemption has been granted could also be considered for exemption from authorization (e.g. exemptions 5a-b, 7c-I, 13a-b, 29).

1. Definition of Lead Special glass and Lead Crystal Glass

Lead Special Glass and Lead Glass are UVCB substance, as recognized in the REACH Regulation : "According to the scientific literature, glass is the state of a substance rather than a substance as such. For legislative purposes, it can best be defined through its starting materials and production process, similar to many other UVCB substances"[5]. The UK REACH Competent Authority further clarified that "glass is to be considered to refer to those materials commonly called glasses"[6].

Lead Special glass and Lead Crystal Glass are substances of variable composition, which just for simplicity is expressed by convention in terms of oxide of the constituents' elements (SiO_2, Na_2O, K_2O, PbO, etc).

Although conventionally glass compositions are expressed as oxides of the different components, glass is a non-crystalline or vitreous inorganic macromolecular structure, which does not contain the individual different oxides; i.e. the different oxides (SiO_2, Na_2O, K_2O, PbO, etc) are not present as such

The complex nature of the vitreous state - thermodynamically as well as structurally - is not in equilibrium and can be considered as a frozen-in, supercooled liquid (or melt) below a characteristic temperature, the so-called glass temperature or transformation temperature.

The American Society of Testing and Materials (ASTM) has defined oxide-glass as "an inorganic product of fusion which has cooled to a rigid condition without crystallization".

In producing oxide glasses the term "fusion" in the ASTM definition has to be questioned. The starting crystalline ingredients (batch components) of a glass composition do not merely fuse or melt, but undergo complicated chemical reactions and solution processes. The raw materials lose their identity ("mineralogical transformation") during heat exposure due to mutual chemical reactions without any stoichiometric compound formation, thus resulting in a three-dimensional random network structure.

Spectroscopic techniques, such as solid state Nuclear Magnetic Resonance demonstrate the presence of Pb-O-Si bonds in these types of glass. Such bonds do not exist in the raw materials used to make the glass because borates and silicon oxides are added as separate raw materials.

Together with other glasses of similar nature, it is classified in EINECS (European Inventory of Existing Commercial chemical Substances) under the entry "Glass*, oxide, chemicals* " - EC number 266-046-0 and CAS number 65997-17-3.

It has to be noted that, since 1969, the quality of "crystal glass" is protected in Europe by the European Directive on Crystal 69/493/EEC [2]. To be called "crystal", the glass must meet three criteria in composition (expressed in metal oxides by convention), density and refractive index.

[5] REACH Regulation, Annex V and Guidance for Annex V, Entry 11, pp. .38-39.
[6] UK REACH Competent Authority Information Leaflet Number 8 – Exemptions, in www.hse.gov.uk/**reach**/resources/exemptions.pdf, *p.5*

This Directive has been integrated into the national legislation of all 28 EU member Countries and serves as a guideline well beyond the boundaries of the EU. This regulation aims to guarantee the authenticity and quality of the crystal articles for the consumers.

2. Manufacturing of the Lead glass and Production of the Lead Glassware are two separate processes

In all factories, the manufacturing of the Lead Special and Lead Crystal glass and the production of the Lead Special and Lead Crystal Glassware occur in **two separate steps** :

- ⇨ The "hot end" process is the manufacturing of the Lead Glass melt, which will be used to form ribbons, droplets or gobs (molten state). In both cases, the Lead glass is still non-shaped, and not adapted to any specific use.
- ⇨ After shaping, the functionalities and the final article are obtained during the following "cold end "process, which produces the Lead Glassware. For the sake of clarification, the "cold end "process could include some further steps at relatively high temperatures, such as re-melting, welding, annealing, etc.

3. Manufacturing process of Lead Glass

The manufacture of Lead glass, be it crystal or special glass, is covered by the Industrial Emissions Directive and is technically explained in the BREF-Document on Best Available Techniques in the manufacture of glass [3].

Glass industry raw materials are largely solid inorganic compounds, either naturally occurring minerals or synthetic products.

The raw material ingredients are melted and react together to be transformed into a new substance: a molten glass at high temperature (ca 1350-1550°C) in furnaces. The obtained Lead Glass melt is then cooled down and delivered in ribbons, droplets or gobs. In a further step, the Lead glass is shaped by different forming techniques, for instance pressing or blowing.

The process layout of the Lead glass Production is reported below:

Mixture of PbO or Pb_3O_4 (original substance) + other raw materials

↓

Lead Glass melt (target substance)

↓

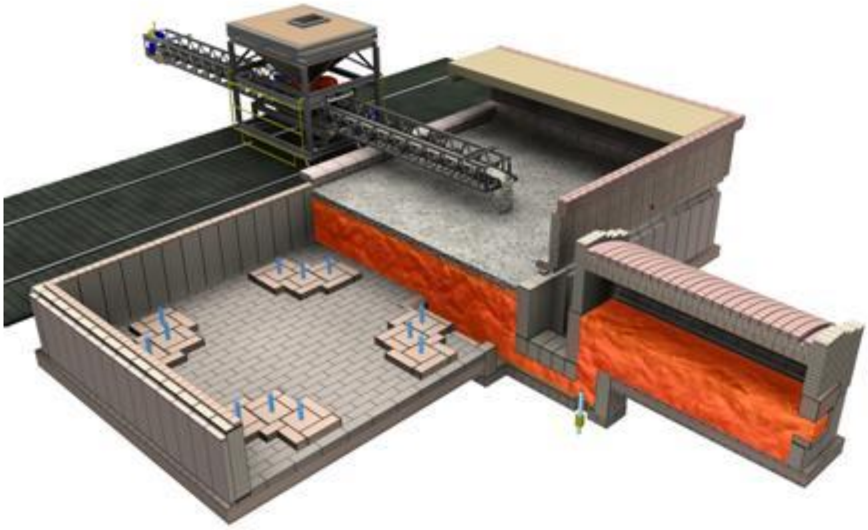
gob (unshaped defined amount of Lead Glass)

↓

Lead glass article (after shaping and finishing operations)

The main steps in the **manufacturing process** of Lead glass are described next:

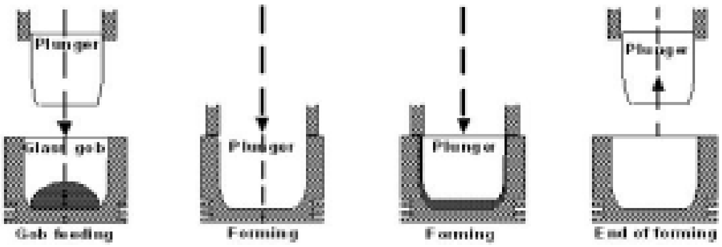
1. The raw materials (e.g. PbO or Pb_3O_4) are delivered by tanker or truck and fed into a silo. They are mostly delivered in closed systems (dosed manually in a small number of cases). Weighing procedure is generally done automatically.
2. In most glass manufacture, the different raw materials that are necessary to obtain the final desired composition of the Lead glass, are individually fed into the balance cone and then mixed automatically with all other raw materials. The batch of raw materials is fed to the entrance (charging end) of the furnace.
3. The melting process can be obtained in pot furnaces, for small discontinuous scale manufactories, or in big continuous melting tank furnaces for continuous industrial manufacture. In this case, continuous cold-top electric furnaces [4] are often used, which are considered as BAT [3] for glass manufacture for installations above 20 tonnes per day. An electric furnace consists of a refractory lined box supported by a steel frame with electrodes inserted either from the side, from the top or, more usually, from the bottom of the furnace. The energy for melting is provided by resistive heating as the electric current passes through the melt. The furnace is operated continuously. The top of the glass bath is covered by a layer of batch material, which gradually heats and melts from the bottom side of the batch blanket upwards, hence the term "cold-top" melter. Fresh batch material is continuously charged on top of the melt surface, usually by a conveyor system that moves across the whole surface. Bag filter systems are required under the Best Available Techniques Reference Document and have excellent environmental performance in terms of direct emissions [3].



4. The molten homogeneous substance is first gradually cooled down. During this cooling step, there is a rapid cooling of the glass mass by contact with air.

4. Production of Lead Glassware

Lead glass, be it Crystal or special glass is then shaped by a large variety of processes, including pressing or blowing. The pressing process is relatively simple. As shown in the figure below, it involves pressing a hot glass gob between a mould and a plunger. [3]



For handmade articles by blowing, Lead Crystal glass melt is gathered by a person with a hollow pipe, either directly from the furnace or from a feeder. A small hollow body of glass (the parison) is made by giving a short puff into the pipe, and the shape is then formed by turning in a wet wooden or metal mould. After forming, the items are carried to an annealing lehr to eliminate any internal tensions and are fire finished, polished and reheated. In semi-automatic production, most of these steps of the process (gathering, forming, and handling) are carried out with machines or robots.

Following the production of the basic items, they can be subjected to one, or frequently more, finishing operations, including mostly cutting, but also decorating with enamels, frosting by sandblasting or acid etching, and engraving [5].

5. Properties of Lead Glass

The main properties of Lead Special Glass are:

- protection against nuclear radiations (nuclear power industry and medical applications),
- high thermal conductivity to avoid distortions due to temperature gradients in the lens or prism
- High p% transmittance at shorter wavelengths to avoid distortions which could lead to inaccurate measurements
- Optimum temperature stabilisation which compensates for image distortion
- Optical transceivers, optical amplifiers, optical isolators
- High quality illumination for microsurgery,
- High transmission performance in lenses of multiple elements

The main properties of Crystal Glass are:

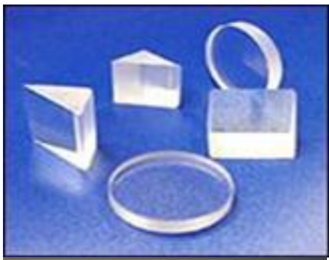
- Insolubility in water, acids and bases;
- Optical properties in certain defined ranges: transparency , light dispersion , refractive index;
- Longer working range allowing the production of articles otherwise impossible to obtain
- Ability for cutting.

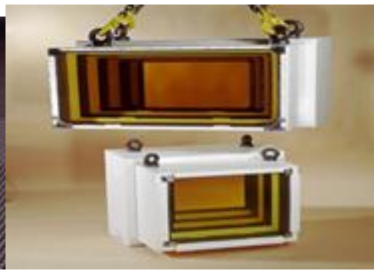
6. Downstream uses of Lead Special Glass and Lead Crystal Glass

Lead Special Glass has numerous applications :

- in medical and industrial applications so that the operator can view the part or patient without being exposed to radiation. In most cases, the radiation attenuation of the glass must be a least equal to the wall or barrier in which the window is located.
- In nuclear safety applications
- in varying percentages of lead content to raise the refractive index in optical and ophthalmic glass. This makes it possible for persons with severe eye problems to see and allows special applications.
- in order to meet the highest demands in relation to optical imaging performance, leaded glass types are extremely important on the basis of their combinations of specific characteristics. Alternative approaches require additional input in terms of more lens elements, which leads to a marked competitive disadvantage in relation to competitors.
- Lenses for high performance binoculars and telescopes having electrical functions
- Optical systems designed for telecom applications in the near IR spectral range from 1000 to 1500 nm
- Digital projectors and rear projection televisions. Lead glass lenses and prisms are used because these are the only types of glass that have high % transmission at shorter wavelengths and do not cause distortion of the image when the glass temperature increases by heating from the intense light source. This is because the refractive index is less affected by temperature changes than lead-free glasses. Heating the glass also affects focusing of the image causing distortion but lead glass lenses can compensate to avoid distortion.
- Temperature compensated high end optical imaging systems for medical applications and for printing and photolithography applications used for industrial tools
- Optics used in instruments used for applications and diagnosis in the near UV-region such as bio-fluorescence, gene analyses and print-scanners
- Spectrometers (visible and UV light) used for analysis and for environmental monitoring
- Polarimeters are used to characterize the optical activity of substances. This is for example important for enantiomeric purity control of pharmaceutical substances to prevent harmful secondary effects of enantiomeric contaminations like in the Contergan-scandal from 1957 to 1962.
- Relay lens **–** these are used to invert images and are used in periscopes, endoscopes, telescopes, microscopes, etc.
- CNC video measuring systems, which are used to measure the dimensions of very small objects such as engineered parts such as for aircraft, e.g. precision made fuel valves and small watch components, silicon wafers for semiconductor and MEMS devices.
- Light guides and lenses for optical microscopes, endoscopes and in IVD equipment. Lead in the glass is needed for high % transmittance at shorter wavelengths, high refractive index and as it has the anomalous dispersion properties required for chromatic aberration compensation. Lead-glass light guides are also used for other applications. Microscopes are used for many different areas of technology.
- Optical telecommunications lenses, such as in optical transceivers, light collimation, optical amplifiers, switches, isolators and transponders

- Laser optics for commercial printers. Large cylindrical lenses are used which must be lead-glass for optimum temperature stabilization






The possible main downstream users of special glasses are: aerospace industry, nuclear industry, medical device industry, telecommunications industry, photographic, video and cinema industry, optical industry, printing industry.

The main application of Lead Crystal glass is the production of tableware, or of decorative glassware, as luminaries, chandeliers, paperweights, jewellery... [5].








7. Use of lead oxide and lead tetraoxide as intermediates of Lead Special glass and Lead Crystal Glass

References [6] to [18]

7.1 - The context: intermediates according to REACH

The term "intermediate" is defined in Article 3 (15) of REACH as "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis)". REACH distinguishes between "non-isolated" and "isolated" intermediates which are further divided into on-site non transported and transported intermediates (Article 3 (15a to 15 c) REACH).

Isolated intermediates are substances which are destined to undergo further chemical reaction on their own or after mixing with other substances. Isolated intermediates may be manufactured at the same site where the reaction takes place ("on-site isolated intermediates"), or transported to that site from another site ("transported isolated intermediates").

Certain lead crystal glassware are used for food contact materials applications and as such comply with Art. 56(5) on substances classified as hazardous to human health used for food contact materials (Reg. 1935/2004). These applications are therefore out of the scope of authorization.

7.2 - Raw Materials used

The oxides needed for the glass are added as a wide range of different raw materials: naturally occurring minerals and man made chemicals. Glass raw material batch may be formulated in different ways, but the properties of the glass depend only on the final composition, not on the individual raw materials that are used to synthesize glass via a melting and reaction process.

7.3 - Batch Reactions

For lead glasses, it is possible to write a general equation to describe the batch reactions and conversion of a multi-component batch into a single melt:

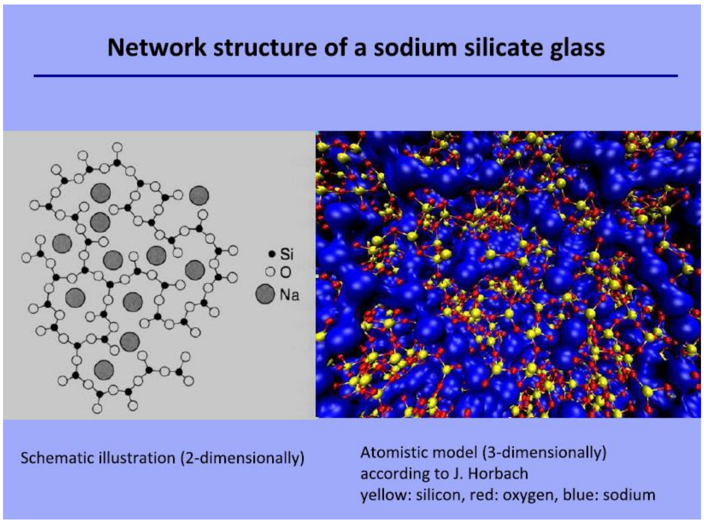
**a SiO_2 [sand] + c Na_2CO_3 [soda] + d Al_2O_3 [alumina] + f K_2CO_3 (potas) + e PbO (litharge) +…..
→x Si(m)Na(o)Al(p), K(q), Pb(r)……. O(s) [glass melt] + y CO_2 ↑ + …..**

Upon cooling at reasonable cooling rates these melts become a glass.

7.4 - Glass Chemistry

Glass is homogeneous and amorphous; no individual components can be identified by analytical techniques such as optical microscopy, scanning electron microscopy and X-ray diffraction. The interaction of glass with other media, e.g. water or aqueous solutions is different for the interaction of these media with the pure raw materials used to melt the glass. Even if glass melt is allowed to crystallize by controlled slow cooling, which is generally not practised, then the crystalline phases produced are not the same as the original batch raw materials. Phase equilibria for all glass-making systems are published and can also be calculated for specific compositions using thermodynamic modelling; e.g. FactSage Gibbs energy minimization software.

Important effects can be measured and modelled and provide insights into the chemistry and properties of glass. Alkali oxides for example, added to silicate glass create non-bridging oxygen that affect network connectivity and thus important glass properties such as viscosity, chemical durability, electrical conductivity and thermal expansion. In conclusion, published research on the bonding and molecular structure of glass clearly establishes the role of chemistry and chemical reaction routes in glass formation.



7.5 - Specific evidence on the structure of Pb glasses Chemistry

The relatively recent progress in spectroscopic techniques, such as solid state NMR, has allowed gaining deeper insights in the structure of Pb glasses. The papers given by ref. [15] to [18] demonstrate in particular the presence of Pb-O-Si bonds in these glasses – such bonds cannot be present in the raw materials used to make these glasses because lead oxides and silicon oxides are added as separate raw materials.

8. Legislation

Lead oxide and lead tetraoxide are already heavily regulated under EU legislation.

It is proposed to consider the following elements when deciding whether to include an exemption of a use of a lead oxide and lead tetraoxide in the ECHA recommendation

(i) There is existing Community legislation[7] addressing the use of lead oxide and lead tetroxide in the manufacture of glass.

(a) *Existing lead specific Community legislation exists for this industrial use of lead monoxide, lead tetroxide in glass manufacturing, as follows*:

- Council Directive 98/24/EC on the protection of the health & safety of workers from the risks related to chemical agents at work (CAD), as implemented by Directives 2000/39/EC, 2006/15/EC, 91/322/EC and 2009/161/EU establishing lists of indicative occupational exposure limit values in implementation of Directive 98/24/EC as amended

- Council Directive 92/85/EEC - Protection of pregnant/breast feeding workers

- Council Directive 94/33/EC on the protection of young people at work

- The Industrial Emissions Directive 2010/75/EC replacing Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC)

- Council Directive 2008/50/EC on ambient air quality and cleaner air for Europe

- Council Directive 2000/60/EC establishing a framework for Community action in the field of water policy

- Council Directive 98/83/EC on the quality of water intended for human consumption

- Council Directive 2006/118/EC on the protection of groundwater against pollution and deterioration

- Council Directive 86/278/EEC on the protection of the environment, and in particular soil, when sewage sludge is used in agriculture

- Directive 69/493/EEC on crystal glass (prescription of the use of lead in crystal glass

- Commission Regulation 836/2012 amending Annex XVII to Regulation 1907/2206 as regards lead (: Entry 63.4 : by way of derogation, the prohibition of the placing on the market and use of lead in jewellery articles with a lead concentration equal or superior to 0.05% in weight 1 does not apply to crystal glass as defined in Directive 69/493/EEC)

[7] Only existing EU legislation is relevant in the context to be assessed (not national legislation).

(ii) This Community 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.

Lead monoxide and lead tetroxide were identified as a Substance of Very High Concern (SVHC) according to article 57 (c) as they are classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1A, [H360D ("May damage the unborn child")], and were therefore included in the candidate list for authorisation on 19/12/2012, following ECHA's decision ED/169/2012. It is this intrinsic property that can result in their proposal for inclusion in Annex XIV.

It is therefore important to assess whether existing community legislation already properly controls risks to human health and the environment arising from this intrinsic property. In doing so, ECHA has to conduct a detailed assessment of the relevant legislation so as to determine not only whether such legislation exists but also whether it sets out measures that already adequately control the relevant risks. Such assessment must be conducted by ECHA *in concreto* on a case-by-case basis. This analysis is described below:

a. Worker health controls

The health hazards of lead monoxide and lead tetroxide are well established and an EU wide harmonised classification exists through an entry in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008. This triggers requirements for specific packaging and labelling and through REACH article 31 the provision of Safety Data Sheets to provide downstream users (including workers) with information on hazards and risk management measures.

During the industrial use of lead monoxide and lead tetroxide in glass production, the health risk associated with lead exposure is properly controlled by the specific requirements of three of the aforementioned legislative acts: Council Directive 98/24/EC on the protection of the health & safety of workers from the risks related to chemical agents at work; Council Directive 92/85/EEC – Protection of pregnant/breast feeding workers; and Council Directive 94/33/EC on the protection of young people at work.

- **Council Directive 98/24/EC on the protection of the health & safety of workers from the risks related to chemical agents at work**

The Chemical Agents Directive (CAD) seeks to protect workers from the effects of chemical agents that are present at the workplace or as a result of any work "activity involving chemical agents", which is defined as "any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work". This would include the industrial use of lead compounds in glass production. The risks to the health of workers at work that is linked to occupational exposure to lead are controlled (in particular) by the imposition of a *binding* occupational exposure limit of 0.15mg/m^3 as specified in Annex 1 to the Directive and a *binding* biological limit value of 70µg Pb/dL blood and health surveillance measures. Lead (and its ionic compounds) remains the only substance listed in the CAD for which binding occupational exposure and biological exposure limits are mandated.

Article 10 of Directive 98/24/EC, indicates that where a binding biological limit value has been set for a chemical, health surveillance is compulsory and employees shall be informed of this requirement before being assigned to the task involving risk or exposure to the hazardous chemical agent indicated (currently this is only relevant to Lead and its ionic compounds).

These binding limits are clearly sufficient to adequately control the risks from lead oxide and lead tetraoxide used in glass manufacturing; in fact, they even go beyond imposing *minimum community wide standards* on Member States by way of establishing harmonized occupational exposure limits.

Looking at those measures *in concreto* reveals that regular exposure reports and studies are collected by several Member States authorities on a yearly basis [see UK HSE statistics at http://www.hse.gov.uk/Statistics/causdis/lead/lead.pdf] that show that the glass industry fully complies with these exposure limits and that, as a result, any risks to workers' health are already adequately controlled.

Moreover CAD also defines additional measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks presented by lead and lead compounds throughout the EU. This is highlighted by the requirements outlined in Articles 4 to 11 and Annex II to the Directive, which impose positive obligations on the employer, to be assessed against measurable indicators. For instance Annex II specifies that biological monitoring of lead exposed workers *must* include measuring blood lead levels using absorption spectroscopy (or an equivalent method), and detailed medical surveillance *must* be carried out if exposure to lead in air is greater than $0.075 mg/m^3$ (8hr TWA) or if a blood lead level greater than 40µg/dL is measured in individual workers. Thus mechanisms exist to identify and, if necessary, remove workers should risks from lead exposure be such that occupational ill-health could result and before any statutory limits are exceeded.

- **Council Directive 92/85/EEC – Protection of pregnant/breast feeding workers**

As lead monoxide and lead tetroxide are classified as Toxic for Reproduction, Category 1A, [H360D ("May damage the unborn child") it is important to evaluate whether this intrinsic property is adequately addressed by existing Community legislation.

Moreover, in the recent RAC opinion for harmonised classification of *lead metal* it was concluded that effects on or via lactation (Lact. - H362 (R64)) should be considered in a harmonised classification proposal as a result of evidence in humans that under extreme conditions levels of lead in breast milk could exceed WHO guidelines. This opinion could also be extrapolated to other lead compounds.

Specific risks to the unborn child and to infants that are breastfeeding are addressed by the requirements of Article 6 to Directive 92/85/EC that *specifically lists* lead and lead derivatives (in Annex II A and B) as substances for which pregnant workers and workers breastfeeding are *prohibited* from exposure if a risk assessment has indicated exposure would jeopardise safety or health. In specifically listing lead and its compounds as substances impacted by the requirements set out in Article 6 prohibiting exposure, we believe that this Directive also imposes *binding minimum standards* for protection of pregnant and breastfeeding workers to lead compound exposure that are applicable across the EU.

- **Council Directive 94/33/EC on the protection of young people at work**

It has been proposed that the developing brain of young people is particularly sensitive to the effects of lead.

It is therefore re-assuring that this element of risks to workers is also covered by long standing Community legislation in the form of Council Directive 94/33/EC on the protection of young people at work. Article 7 (2) b ensures that Member States prohibit the employment of young people for work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage or harm to the unborn child or which in any other way affects human health. Lead and its compounds are *specifically described* in Annex to this Directive as agents for which Article 7 (2) applies.

b. Environmental controls

Although the proposal for inclusion of lead monoxide and lead tetroxide in Annex XIV relates predominantly to health risks it is also relevant to report that manufacturing facilities using lead and compounds are also covered by existing Community legislation ensuring that environmental releases are appropriately managed.

- **Ambient Air Quality Directive 2008/50/EC**

The Air Quality Directive requires that ambient air quality *must* be monitored throughout the territory of the Member States, who must ensure that the levels of lead in ambient air do not exceed the limit value of 0.5μg/m^3. In doing so this legislation can be seen to meet the requirement to specifically refer to lead compounds and set a minimum requirement for control of risk in establishing a limit value for lead in Annex XI that Member States shall ensure ambient air does not exceed.

- **The Industrial Emissions Directive (IED) 2010/75/EC**

This Directive is a recast of six previous directives concerning integrated pollution prevention and control (2008/1/EC12), waste incineration (2000/76/EC), solvent emissions (1999/13/EC) and three concerning waste from the titanium dioxide industry and sets out to achieve a high level of protection for the environment taken 'as a whole' from harmful effects of industrial activities. As from January 2016 IED will also replace Directive 2001/80/EC on the limitation of emissions of certain pollutants from large combustion plants. The key processes in manufacturing glass are regulated directly by requirements of the IED.

Permit conditions and pollutant emission limit values (ELVs) therein have to be set on the basis of the application of best available techniques (BAT). Competent Authorities shall set emission limit values that ensure that, under normal operating conditions, emissions do not exceed the emission levels associated with the best available techniques as laid down in the decisions on BAT conclusions. Binding EU-wide Associated Emission Limit Values (A-ELVs) have recently been established for several industries manufacturing or using lead. The processes of manufacturing glass are regulated directly by IED requirements.

- **Water Framework Directive (WFD) 2000/60/EC**

The WFD commits European Union Member States to achieve good qualitative and quantitative status of all water bodies (including marine waters up to one nautical mile from shore) by 2015. The strategy for achieving this involves the identification of priority substances amongst those that pose a significant risk to, or via, the aquatic environment at European Union level. The Water Framework Directive foresees in its articles 16 and 17 two crucial Daughter Directives, on quality of groundwater and on quality of surface waters. The Priority Substances Directive (2008/105/EC) lists lead and its compounds and lays down associated Environmental Quality Standards (EQS) that Member States should take into account for the first time in river basin management plans covering the period 2015 to 2021. Inclusion of a lead EQS in the Priority Substances Directive meets in our opinion the REACH article 58(2) requirement to specifically mention the substance and establish a Europe wide standard.

(iii) This Community legislation imposes minimum requirements[8] for the control of risks of the use. 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.

From the analysis made above it would appear that the existing workplace legislation for lead imposes specific minimum requirements for the control of health risks of the **industrial use** of the lead oxide and lead tetraoxide used in glass manufacturing. Whilst not directly applicable to the intrinsic hazards for which inclusion in Annex XIV is being considered (i.e. reproductive toxicity) it is also evident that existing environmental legislation contains elements intended to properly control the risks to human health and/or the environment resulting from release of lead from glass manufacturing facilities.

- **Other "Lead-Specific" EU Legislation**

<u>Exemptions granted under ROHS</u>

REACH aims to ensure that the risks presented by substances are adequately controlled throughout their whole life cycle, including those occurring in the waste stream. The Directive on Restrictions of Hazardous Substances in electric or electronic equipment (RoHS – 2011/65/EC) contributes in addition to the sound management of waste of electric and electronic equipment by limiting or prohibiting specific applications.

Lead used in the manufacture of electric or electronic equipment made of lead crystal glass and lead special glass was granted exemption to the ROHS Directive for several applications (e.g. exemptions 5a-b, 7c-I, 13a-b, 29). The ROHS Directive already requests that substitution

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[8] There needs to be binding and enforceable minimum requirements in place for the substance(s) used. Legislation imposing minimum requirements means that:

- The Member States may establish more stringent but not less stringent requirements when implementing the specific EU legislation in question.

- The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as appropriate.

be sought, and information are submitted and taken in consideration in this respect in the requests for exemptions.

The glass manufacturing industry suggests that exemptions from authorization should be recognized on the basis of the "Common Understanding"[9] document between ECHA and Member States, which says that :

> *Where RoHS provides for exempt applications (so that certain EEE containing a given substance may be placed on the market in specified cases), the incorporation of that substance in EEE by EU manufacturers would be subject to the authorisation procedure under REACH. However, the possibility is also open to exempt the uses covered by the RoHS restriction (including its exempted applications) from the authorisation process under REACH pursuant to Article 58(2) of REACH on the basis of the arguments described above.*
>
> *An additional issue to be considered where RoHS provides for exempt applications is whether the pressure to substitute would be lost if the incorporation of substances in EEE was exempted from the REACH authorisation requirement. In this regard, it should be noted that decisions taken under Article 5 of RoHS to include materials in Annexes III and IV (exempt applications) must take into account the practicability, reliability or socioeconomic impact of substitution. Moreover, the exemptions are time limited and will only be renewed after submission of the information listed in Annex V to RoHS, including updated details of the practicability and reliability of substitution, an analysis of possible alternatives and a timetable for action to develop /apply possible alternatives. All of these requirements may be seen as mirroring the substitution objective of the REACH authorisation procedure.*

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