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IMPACT ASSESSMENT

Accompanying document to the

COMMISSION REGULATION (EU)

Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) as regards Annex XVII (Cadmium)

Lead DGs: Enterprise and Industry, Environment

Agenda planning or WP reference: 2006/ENTR/011

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Disclaimer:

This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

Background

Council Resolution of 25 January 1988 (88/C 30/01) invited the Commission to combat environmental pollution by cadmium. As a consequence, Council Directive 91/338/EEC amending Directive 76/769/EEC on restrictions to the marketing and use of dangerous substances and preparations prohibited the marketing and use of cadmium pigments and stabilisers in a wide range of products. The cadmium plating of a number of metallic products was also prohibited.

Directive 76/769/EEC was repealed and replaced by Regulation (EC) No 1907/2006 (REACH)[1] . The above mentioned restrictions on cadmium are incorporated in entry 23 to Annex XVII to REACH. Currently, there is no restriction on the use and marketing of cadmium-bearing brazing alloys and jewellery in Annex XVII. Regarding PVC, Annex XVII only contains a restriction to a threshold of 100 ppm for cadmium (limit of 0,01%) on the use and placing on the marketing of cadmium as stabiliser for PVC for a number of applications[2].

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, until its repeal by REACH in June 2008, involved the data reporting, priority setting, risk evaluation and, where necessary, development of strategies for limiting the risks of existing substances. In this regard, cadmium and cadmium oxide have been identified as priority substances for a risk assessment.

The risk assessment pursuant to the Regulation, performed by Belgium, has been completed and a risk reduction strategy for limiting the identified risks has been adopted in 2008[3]. Communication 2008/C 149/03[4], together with the corresponding Commission Recommendation 2008/446/EC[5], provide the results of risk evaluations and strategies for limiting the risks for the above mentioned substances. The conclusion of the assessment of the risks to consumers is that there is a need for specific measures to limit the risks in brazing materials and jewellery. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted and has issued opinions with respect to the risk evaluations carried out by the rapporteurs. These opinions, which have been taken into account during the formulation of the risk reduction strategy mentioned above, can be found on the website of the Scientific Committee[6].

For brazing applications alternatives are available except for specific application in the aerospace and defence industry. For jewellery there is no need to use cadmium, it is present as impurity or fraudulent replacement of more expensive precious metals.

Concerning PVC, in recent years, efforts have been made both by authorities and industry to reduce the presence of heavy metals, amongst which cadmium, in PVC articles. Moreover, the technological and scientific progress regarding substitutes has enabled plastics producers to substitute cadmium based stabilisers in all PVC products. This substitution has been

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1 REACH is the Regulation about the registration, evaluation and authorisation of chemicals. Please note that a glossary with acronyms and the explanation of technical terms can be found in annex 1.

2 These applications are listed under section 2.1.3.

3 European Union Risk Assessment Report cadmium metal and cadmium oxide Part I environment (EUR 22919 ENV, Part II Human Health (EUR 22766 EN)

4 O.J. C 149 14.6.2008 p. 6

5 O.J. L 156 14.6.2008 p. 22

6 http://ec.europa.eu/health/ph_risk/committees/sct/sct_opinions_en.htm

formalised by the Vinyl 2010 voluntary commitment, in which the PVC industry committed itself not to use cadmium as a stabiliser in PVC after 2001. This voluntary commitment goes beyond the regulatory requirements for cadmium as stabiliser for PVC in a number of specific applications.

In view of the general objectives to support the EU waste policy in favour of recycling and the phase out of the use of cadmium, it is appropriate to review uses of cadmium as a stabiliser in PVC products not yet restricted under REACH in view of further restrictions, while being mindful of the growing interest in recycling of PVC waste and its potential benefits and drawbacks.

Following the provisions of Article 137[7] of REACH and as a consequence of the risk assessment and the risk reduction strategy adopted in 2008, this Impact Assessment will assess the need for a draft Commission Regulation amending Annex XVII to REACH as regards the restriction on cadmium.

Section 1: Procedural issues and consultation of interested parties

1.1. Consultation and expertise

For the socio-economic assessment the Commission (DG ENTR) contracted a socio-economic assessment study from Risk & Policy Analysts Limited, (RPA Ltd)[8].

The study analyses the socio-economic consequences covering economic impacts on businesses and consumers, impacts on health and the environment, other social implications and wider impacts on trade, competition and economic development of several options and compares them to the baseline of 'no action'.

The consultant has had extensive contacts with experts from numerous stakeholder organisations, such as Member States, trade associations and industry (including SMEs), between April and September 2009 (see Annex II). The stakeholders have mainly been consulted by e-mail, using questionnaires adapted to each category of stakeholder. In addition for the PVC industry telephone conferences were held with some trade associations.

In addition to the contacts established by RPA the Commission services have contacted the SME contact points of the European Enterprise Network to encourage them to fill the RPA questionnaire that was available on the internet. Unfortunately no inputs were received.

The reactions on the preferred options (i.e. banning of cadmium from brazing materials and jewellery and ban for cadmium in PVC, except for certain building applications for which there would be a limit of 1,000 ppm) can be summarized as follows:

– For brazing materials there were mixed reactions, positive from those stakeholders that are already replacing cadmium, and negative from those manufacturers and users that are still producing/using cadmium-bearing alloys.

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7 Art. 137 of REACH deals with the transitional measures regarding restrictions

8 Socio-Economic impact of a potential update of the restrictions on the marketing and use of cadmium, Final Report, December 2009, **Risk & Policy Analysts Limited,** Loddon, Norfolk, UK. http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/studies/index_en.htm

– For jewellery limited input was received from EU and non-EU trade associations. A small number of EU companies feared that they would no longer be able to purchase and use jewellery containing small levels of the metal.

– For non-EU organisations the reactions depended on the belief that such a restriction would have a negative impact on their possible exports to the EU. EU manufacturers of jewellery and alloys fear the raise of cost of alloys.

– For PVC the industry is keen to continue to use PVC recyclate (often containing cadmium), but some concern is expressed on the proposed 1,000 ppm limit for building products containing recycled PVC, which could be too low according to some stakeholders and the timeframe too short.

All potential measures have been discussed with the other relevant Commission services. DG ENV and DG SANCO were consulted already before the launch of the study carried out by RPA. An Impact Assessment Steering Group to which the SG, DG SANCO, DG ENV, DG EMPL, DG RTD, DG AGRI, DG RELEX, DG TRADE, DG ECFIN were invited was set-up and met 3 times, on 13 January, 10 and 18 February 2010.

1.2. Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the impact assessment and issued its opinion on 26 March 2010. The Impact Assessment Board made several comments and, in the light of those suggestions, the final Impact Assessment report:

– clarifies the conclusions and makes them more accessible to the general audience,

– adds additional evidence that is relevant for decision making,

– provides a more prominent discussion of coherence with other policies and stakeholder views.

Section 2: Problem definition

The problems for jewellery and brazing are different from the problem of PVC. Therefore these are described under different headings. For brazing and jewellery the main problem is the release of cadmium that has an effect on human health and the environment. For PVC the main problem is, while extending the prohibition of the use of Cadmium to all articles made from PVC, to allow recycling of cadmium containing PVC which is not possible with the current restriction und thus would have negative impact on the environment.

2.1 Exposure to cadmium for humans and the environment

Cadmium is a CMR substance (carcinogenic, mutagenic or toxic for reproduction). According to the CLP Regulation (EC) No 1272/2008 Annex VI it is a type 1B carcinogen (presumed to have carcinogenic potential for humans, classification is largely based on animal evidence), a category 2 mutagen (substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans) and reproductive toxicant (suspected human reproductive toxicant).

In the Commission Recommendation (2008/466/EC), that was published following the risk assessment on cadmium and cadmium oxide, risk reduction measures for workers and the environment were proposed, see section 2.2.

The Communication from the Commission published following the risk assessment (2008/C 149/03) contains the results of the risk assessment and identifies specific needs for measures for workers, consumers and the environment. It also recommends considering a specific strategy for limiting risks for consumers coming from marketing and use of brazing sticks which contain cadmium and of jewellery containing cadmium intended to come into contact with the skin.

In parallel, various other EU policies in order to reduce exposure to cadmium already exist or are being prepared (see Annex III).

Exposure to cadmium from brazing materials and jewellery for workers and consumers comes from through inhalation (fumes) and skin contact. Environmental exposure comes from release of cadmium into the environment through fumes, waste and accidental release.

For PVC, release from cadmium into the environment from PVC produced before the voluntary ban in the EU, might take place. The release comes from leakage of cadmium out of PVC waste during landfill (limited but can not be excluded) or through incineration (in the filters containing the fly ashes). The main advantage of recycling, beyond its economical value, is that cadmium release will be spread over a longer time period and that there will be a reduction of release of CO_2.

2.1.1 Brazing Alloys

Brazing is a joining technique that uses alloys with liquidus temperatures[9] which are above 450 °C (BrazeTec, 2007). Brazing itself is sub-divided into low temperature brazing (also known as 'hard soldering'), generally accepted as being up to 1,000 °C, and high temperature brazing, often using precious metals and nickel, where the temperatures are in excess of 1,000 °C (Heathcote, 1981). Soldering is undertaken at temperatures below 450 °C and should not be confused with brazing.

Cadmium in its solid form alloyed with other metals presents little danger but potential hazards start when the alloy containing cadmium melts at 321°C (boiling point of 767°C) and cadmium may be released as a gas. The higher the temperature cadmium metal is exposed to, the higher its vapour pressure, hence the higher the volatilisation and the formation of dangerous cadmium oxide fumes. Conditions encountered during melting operations, brazing activity and jewellery bench soldering often exceed the boiling point of cadmium, occasionally with inadequate ventilation, greatly enhancing the risk of exposure. (HSE, 1999; CUP Alloys, 2009c).

Cadmium-bearing brazing alloys find numerous applications. The key consumer use of cadmium-bearing brazing alloys is in model engineering (e.g. copper boiler manufacture). Professional use is identified in tooling, heat exchangers, heating, ventilation and air

[9] The liquidus temperature is the upper temperature limit of the melting range or the melting interval. The brazing alloy is completely liquid above this temperature. On the other hand, the solidus temperature is the lower temperature of the melting range or melting interval. The brazing alloy is completely solid below this temperature (BrazeTec, 2007).

conditioning (HVAC) and refrigeration, plumbing and electrical components. It is estimated that, in the EU, consumers use around 10 tonnes of alloys per year (containing up to 2.5 tonnes of cadmium) while professional users consume around 90-140 tonnes of alloys per year (containing up to 22.5-35 tonnes of cadmium). The use of cadmium bearing alloys seems to be concentrated in the UK (DIY use) and some southern Member States (professional use) (RPA, 2009).

Cadmium free alloy cost on average 20% more then cadmium-bearing alternatives and marginally prolonged brazing periods and higher temperatures are needed (RPA, 2009). Also, users need to change old habits but there has been a trend among professional users since the 1970s to steer clear of cadmium-bearing alloys and many professional users have now successfully abandoned cadmium. Moreover, companies are expected to unilaterally apply the new ISO standard 17672 on brazing – filler metals in which the use of cadmium bearing filler materials is recognised as hazardous and should be substituted by cadmium free materials. Only for very specific safety critical applications, such as aerospace and defence[10] no alternatives are available for cadmium in brazing alloys.

The use of cadmium-bearing brazing fillers may result in exposure of the user to cadmium oxide fumes. For professional users the EU policy on protection of workers, Framework Directive 89/391/EEC, is based on the approach that workers exposure should be eliminated or where this is not possible the risks should be assessed and appropriate risk management measures introduced with control at source being the preferred control mechanism and PPE used only as a last resort.

Article 16 of the Framework Directive foresees the adoption of individual directives covering specific subjects. In particular, as regards exposure to chemicals EU Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work introduce minimum requirements for worker protection.

These requirements include the establishment of EU Occupational Exposure Limit Values. The EU Scientific Committee on Occupational Exposure Limits has evaluated the health effects of occupational exposure to cadmium and its inorganic compounds and has recommended an EU 8 hour time weighted average OEL of 0.004mg/m3 for the respirable fraction (SCOEL SUM 136/February 2010). At present this value has not been adopted within a Directive though national OELs may exist in several Member States.

It should be possible to effectively control workers exposure by the use of appropriate risk management measures following the hierarchy of control outlined in the directives – preference should be given to eliminating exposure and if this is not possible collective control measures, such as process enclosure or ventilation, should be used and PPE used only as a measure of last resort.

The existing legislation presents a legal framework for the protection of workers from exposure to cadmium but does not cover self-employed persons.

[10] In aerospace and defence the use of cadmium-bearing alloys is required for ensuring the integrity of construction and the attainment of require high safety standards

For consumers, the consequences of the additional cadmium burdens were estimated based on the consequences (in terms of attributable deaths) of elevated urinary cadmium levels above either the EFSA reference level or in excess of the lowest observed adverse effect level (LOAEL) established by the cadmium risk assessment report.

In a calculation made by RPA (RPA, 2009) the maximum corresponding burden for deaths from 'non-cardiovascular causes' in the exposed population was found to be 12.4 cases over the life span of the consumers (the DIY users) across the EU-27 (this translates to 0.62 cases per year based on a 20 year life span for the average hobby user, taking into account the age profile of such users). For professional users, calculations suggest the exposure to cadmium oxide during brazing may lead to 6-29 additional lung cancer deaths per year in the EU-15, as well as 15 additional cases of occupationally induced emphysema in the EU-27.

From brazing activities there may also be a release of cadmium into the environment from fumes, waste or accidental release.

In summary the main stakeholders involved are manufacturers and suppliers of cadmium-bearing brazing alloys, professional users, DIY users (model engineers), professional steam boiler makers, boiler testers, manufacturers and suppliers of fume extractors, suppliers of compressed gases as well as humans exposed to cadmium via the environment and the ecosystems.

2.1.2. Jewellery

For jewellery products there are two main product groups where cadmium may be found (CBI, 2008):

– **precious jewellery** is marked by its exclusive use of precious metal (alloys) and stones and is usually sold in traditional jewellery shops, department stores, tax-free shops and high-class gift outlets

– **costume jewellery** contains a variety of materials and can be found in a wide range of shops, going from specialised costume jewellery shops over department stores to market stalls.

Italy, France, UK, Germany, Spain, Austria, Poland and the Scandinavian countries are the main centres in the EU for precious jewellery and for medium-high quality costume jewellery. Among the new Member States, Poland, Hungary, Czech Republic and increasingly Romania and Bulgaria are producers of silver and costume jewellery with amber and glass beads sold on the market in other Member States[11]. Globally, the jewellery manufacture industry is led by Italy, China, USA, Switzerland, Israel, India and Thailand. China, Turkey and India are emerging jewellery industry centres, with India leading gemstones processing. Costume jewellery mainly comes from China, Thailand, India, USA, Austria, France and Germany (CBI, 2008).

The RPA study shows that the use of cadmium in EU-based jewellery production has ceased but nevertheless still is found in some rare cases. High concentrations appear to be associated with costume jewellery imported into the EU that is usually sold as 'silver or gold' jewellery,

[11] In the EU 22,500 companies in the EU employing 94,000 persons for precious jewellery and 5,350 companies employing 20,000 people in the costume jewellery sector

although the levels of silver and gold are too low for them to be considered 'precious metal' jewellery articles. As such, 273 tonnes of cadmium may be entering the EU on an annual basis in the form of jewellery articles. Cadmium may be present in jewellery as part of the main jewellery alloy, in a solder, in gold coatings (electroforming/electroplating), or as a pigment or stabiliser in non-metal components of a jewellery article. Most jewellery contains low levels of cadmium as impurities but also high concentrations of up to more than 90% have been found in costume jewellery (RPA, 2009).

There are two key issues surrounding the use of cadmium in jewellery. First when cadmium-containing materials are used (essentially cadmium-bearing solders), exposure to cadmium oxide fumes cannot be excluded. Secondly, European consumers are exposed to cadmium in jewellery through skin contact or licking. Most affected are young persons as they are the main costumers of costume jewellery.

There are 2 categories of children at risk (1) very young ones that may suck jewellery, (2) adolescents (13/19 years) that buy cheap costume jewellery that represents a higher risk of containing cadmium. It is not possible to quantify the risk for children but there is a higher risk than for adults because of toxicokinetic and dose related effects. More specifically cadmium is particularly dangerous for children as their growing bodies readily absorb substances and cadmium accumulates in the kidney, where it stays for decades. In addition children have less body weight and a relatively higher surface which is why toxicity is relatively higher.

Although, working women may represent 65% of the value of jewellery sales (in 2007), jewellery is becoming more and more popular with young children and teens aged between 13 and 19. More importantly, pre-teens are reportedly now an important segment for costume jewellery being subjected to the increasing influence of magazines, television, movies, video games and other peer-pressure. Eurostat data show that the age groups of young consumers currently exceeds 80 million across the EU-27 and although it cannot be assumed that all of them would wear cadmium-containing jewellery, the potential 'target' group for jewellery articles leading to cadmium exposure could be quite substantial and could rise in the future.

RPA calculated that the additional number of deaths over the course of the life of the population exposed to custom jewellery 3.0 to 5.9 additional deaths for EU-27 (RPA, 2009).

In summary the main stakeholders involved are manufacturers of jewellery articles, refiners of precious metals, importers, distributors and retailers of jewellery in the EU, consumers as well as humans exposed to cadmium via the environment and the ecosystems.

2.2 Recycling of PVC containing cadmium and its impact on the environment

2.2.1. PVC

Cadmium-bearing stabilisers retard the degradation processes in PVC that occur upon exposure to heat and ultraviolet light. These stabilisers are incorporated into PVC before processing and which arrest any degradation reactions during subsequent processing and ensure a long service life (ICdA, 2009).

In recent years, efforts have been made both by authorities and industry to reduce the presence of heavy metals, amongst which cadmium, in PVC articles and to replace them with alternatives such as calcium/zinc stabilisers.

In Commission Regulation (EC) 552/2009[12] (that transfers Council Directive 91/338/EEC into REACH) certain products made from PVC (*office or school supplies; fittings for furniture, coachwork or the like; articles of apparel and clothing accessories (including gloves); floor and wall coverings; impregnated, coated, covered or laminated textile fabrics; imitation leather; gramophone records; tubes and pipes and their fittings; swing doors; vehicles for road transport; coating of steel sheet used in construction or in industry; insulation for electric wiring*) have a restriction to a threshold of 100 ppm for cadmium (equal to 0.01% of cadmium pure metal by weight of the polymer), which is in fact a total ban leaving room for some minor unintentional or background contamination or measuring differences.

Thus, the current restrictions for PVC under REACH on use of cadmium apply only for the above mentioned limited range of mixtures or articles factored from PVC. Taking into account (1) the Council Resolution calling on the Commission for limitation of the uses of cadmium to cases where suitable alternatives do not exist, as well as (2) the fact that application of cadmium as a stabiliser in PVC has been phased out voluntarily by the European PVC industry, it seems appropriate to assess extending the existing restrictions to all PVC products.

However in this context one has to consider that some of the restrictions reduce the possibility for using recycled PVC. As provided by stakeholders certain building applications are concerned especially[13]. If PVC is not recycled it is discarded (in landfill or incineration) which has a negative impact on environment as well as the recycling and converting industry. Thus temporarily higher concentration limits for cadmium in certain building applications will be considered in the analysis.

The reason why cadmium stabilisers are currently not restricted in profiles for example for PVC window frames, square cable ducts or roofing is that because at the time when Council Directive 91/338/EEC was drafted, it was not technically feasible to replace cadmium as a stabiliser in these applications. Today replacement is possible, which explains the voluntary agreement of the European industry not to use cadmium stabilisers any longer. In 2000, the European PVC industry engaged in a Voluntary Commitment called Vinyl 2010[14] in which, amongst others, the use of cadmium stabilisers has already been phased out in the EU (15) since 2001. Following the enlargement the phase-out in EU-27 was completed by the end of 2007.

The European PVC chain, from resin and additive manufacture to the final product, involves many thousands of companies, of which many are Small and Medium Sizes Enterprises, and probably more than half a million employees, of which approximately 200,000 are directly active in production and converting (ECVM).

As part of this Voluntary Commitment industry has also invested significant resources and effort in establishing and operating schemes for the collection and recycling of rigid PVC. For example, the Recovinyl programme, as part of Vinyl 2010 has shown an increase of PVC

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12 OJ L 164, 26.6.2009, p. 7–31

13 More specifically in roof gutters; pipe fittings and middle layers of 3 or more layer pipes, with the exception of drinking water pipes; roller shutters; rigid sheets for building applications; cladding or cover); blinds; doors; bottom or intermediate layers of multi-layer flooring; sound proofing walls; cable insulation; cable ducts profiles; pallets, box pallets and other load boards.

14 www.vinyl2010.org

being recycled in Europe, starting from 14,000 tonnes in 2005 to reaching 191,393 tonnes in 2008[15]. The average use of recyclate in profiles is 40 % and for pipes 65-100 %[16]. Recycling presently mainly takes place in FR, DE, NL, PL and UK and recyclers are typically SMEs. Currently, a critical point has been reached with old cadmium-containing PVC window (and other) profiles, which have historically contained an average of 2,000 ppm of cadmium, entering the recycling stream as they now gradually start reaching the end of their useful life. If no action is taken, whilst the recycling of waste PVC profiles into new PVC profiles could continue, the recycling of high cadmium-containing recyclate into the other applications subject to restrictions on cadmium would be problematic as the presence of cadmium would increase and lead to the exceedance of the existing 100 ppm limit. As it is difficult to use all the available PVC recyclate for the limited range of applications exempted from the cadmium restrictions, this could have adverse consequences on the recycling of PVC in the EU more generally. For example, the VITO study shows that 3.14 million tonnes could be recycled in addition in the period from 2010-2050 if recycling is allowed in non-pressure pipes. Modelling has shown that in case of recycling the highest possible concentration for cadmium in PVC profiles or pipes will be lower than 1,000 ppm (VITO 2009).

Alternative treatment methods for PVC waste are incineration and in landfilling. In some MS landfilling of untreated waste, including PVC is prohibited, while in others landfilling of untreated PVC is still allowed. Both methods imply a risk of release of the cadmium contained in the PVC to the environment through leakage and fumes. However, the biggest impact on the environment is the release of CO_2 during incineration.

The assessment of the toxicological risk coming from the leakage of cadmium from the recycled products to the environment is based on a review performed by ARGUS (ARGUS 2000). Leakage can be provoked under artificial acid conditions that normally do not exist. The conclusion of this review is that cadmium is a stabiliser that is fixed in the matrix, with a low probability of leakage, but possible leakage can not be completely excluded because of uncertainties in analytical methods. The Commission organised a meeting with representatives of Member States on 26 March 2010 to discuss migration modelling as a tool to assess the migration of cadmium out of PVC. The experts agreed that migration modelling confirms that the migration of the cadmium out of the PVC matrix is very low and a slow process, typically taking more then hundreds of years. Migration levels from multilayer PVC pipes are lower than those from monolayer PVC pipes. In addition in case there is contact with water, the migration level is higher, which necessitates that the recycled PVC is only used in inner layers of multilayer PVC pipes.

In summary the main stakeholders involved are waste collectors, disposers and recyclers, manufacturers of PVC building products as well as humans exposed to cadmium via the environment and the ecosystems.

2.3 EU right to act

REACH, which regulates and fully harmonises restrictions of chemicals, is based on ***Article 114*** of the Treaty. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for

[15] Vinyl 2010 Progress Report 2009

[16] Recyclate is used only in non-pressure pipes (sewer or cable protection) in sewer pipes generally 65% recyclate can be used, for cable protection pipes up to 100% (VITO, 2009).

assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

The nature of the risks from cadmium in brazing sticks and jewellery, in particular their potential to cause serious illness as cadmium is a carcinogen, needs action at EU level in order to achieve a high level of protection of human health and the environment and harmonised rules to reduce such risks.

In addition in view of the general objective to combat environmental pollution by cadmium it is necessary to act at EU level in order to reduce the use of Cadmium in PVC while allowing the recycling of PVC.

In order to ensure a high level of protection of human health and the environment and the free circulation of articles it is necessary to adopt restrictions on cadmium at European Union level. No impact is expected on the EU budget.

Section 3: Objectives

3.1. General objectives

The first general policy objective is to reduce exposure to cadmium for humans and the environment and to phase out the use of cadmium, in a technical and economical feasible manner and to ensure the free circulation of substances in the internal market.

The second policy objective is to support the EU waste policy in favour of recycling.

3.2 Specific objectives

– Reduce exposure to cadmium for brazing alloys or jewellery for professional users and consumers (do-it-yourself users as well as persons wearing jewellery),

– Reduce the release of cadmium into the environment (from fumes formed during brazing activities, waste or accidental release) resulting from the use of products available on the EU market to the lowest level possible,

– Allow a cost-efficient and environmentally friendly management system for PVC waste containing cadmium,

– Support the phasing out of cadmium used as stabilisers in new PVC.

Section 4: Policy options

Several policy options could be used to achieve the intended objective to reduce exposure to cadmium for the general public and the environment. In this section the possible options will be identified, outlined and subsequently screened for their feasibility. Only the most feasible and options will be taken forward for further analysis.

Awareness raising is not considered a feasible action. First of all, for brazing alloys labelling already exists (EUH207 – Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with safety instructions). However, this is not considered as sufficient as lethal cases from DIY use have still been identified. Therefore labelling seems to be insufficient and not enforceable. For jewellery

awareness raising is not considered being a feasible option as consumers are not aware of the cadmium problem.

4.1 Cadmium in brazing alloys

Option B1: Baseline scenario, continuing business as usual

The ‘business as usual’ option would essentially mean that cadmium-bearing brazing alloys would continue to be supplied to consumers and professional users. The main consumer use appears to be for DIY model engineering (e.g. manufacture of steam boilers for miniature trains, boats and other vehicles) and the main professional/industrial uses are identified in tooling, heat exchangers, heating, ventilation and air conditioning, refrigeration, plumbing and electrical components.

Option B2: The complete restriction on the marketing and use of cadmium-bearing brazing alloys

(a) for consumer use only

Under this option, a complete restriction for consumers on the use of cadmium would be introduced under Annex XVII to the REACH Regulation, meaning that DIY users would no longer be exposed to cadmium release from brazing activities. The wording should specify that the restriction targets the marketing and use of cadmium-bearing alloys for use by the general public for DIY applications. Enforcement and monitoring by Member States is difficult because in practice no controls are performed at consumer level. Controls will only be possible at retail level, i.e. at the distributors of alloys. It is also not feasible to segregate the market of consumer brazing from professional use. Therefore this option will be discarded and only the joint option for banning for consumer and professional use will be further evaluated.

(b) for consumer and professional use

Under this option, a restriction on the use of cadmium would be introduced under Annex XVII to the REACH Regulation, meaning professional and DIY users would no longer be exposed to release of cadmium from brazing activities. The wording shall, if necessary, provide some specific exemptions for use in areas that are safety critical and for which no alternatives are currently available on the market. Enforcement and monitoring by Member States will be done at the level of retailers of brazing materials as well as at controls at the workplace.

Option B3 Restriction on the use of cadmium-bearing brazing fillers under prescribed conditions

(a) for consumer use only

This option would aim to reduce the exposure of DIY users to cadmium oxide fumes by specifying use conditions that would reduce the likelihood of exposure to cadmium such as:

- Not to use oxy-acetylene torches as these operate at too high temperature which increases the risk of cadmium release in fumes
- Use of a respirator suitable for brazing applications
- Use of a personal fume extractor
- Undertake brazing strictly outdoors
- A limit on alloy consumption.

(b) for professional use only

This option would essentially be similar to option B3a, but it would only be targeted towards professional users. However, there is currently legislation in place, i.e. the Framework Directive 89/391/EEC, the Chemical Agents Directive 98/24/EC and the Carcinogens and Mutagens Directive 2004/37/EC (see Annex III) regulating the use of hazardous chemicals,

including carcinogens, at work, which requires an assessment of risks to workers from substances and prescribes conditions of use, or, where appropriate, substitution. Therefore, adoption of Option B3b would effectively replicate existing legal requirements for workers. This, however, may not apply to self-employed individuals making the option ineffective. Because of the impossibility to separate the markets the self-employed persons would still be able to acquire cadmium containing brazing materials. In addition, the wide variety of sectors and work places in which these persons are working makes this option difficult to implement and control.

Therefore, because of the overlap with other existing legislation for employed workers and the difficulty to implement the legislation for self-employed workers Option B3b will not be considered further.

4.2 Cadmium in jewellery

The analysed options for cadmium in jewellery are described below. Please note that for all the options the assumption is made that all jewellery can get into contact with the skin.

Option J1: Baseline scenario continuing business as usual

Under this option, the use of cadmium in jewellery manufacture would continue and cadmium-containing jewellery articles would continue to be available on EU markets. Consumers would be likely to continue to be exposed to cadmium in potentially significant quantities through costume jewellery as well. Occasional testing on cadmium should continue to highlight the presence of cadmium in such articles.

Option J2: The complete restriction on cadmium in jewellery articles

Under this option, a complete restriction on the presence of cadmium in jewellery articles placed on the EU market is introduced under Annex XVII of REACH. As such consumers would no longer be exposed to cadmium migration from jewellery. Such a restriction would encompass both precious jewellery articles and costume articles (amongst other reasons, to avoid grey zones and borderline cases arising) and apply to both jewellery articles manufactured in the EU and those imported from non-EU countries. Effectively, the intentional use of cadmium in jewellery applications would be prohibited.

Option J3: Restriction on the cadmium content of jewellery

Under this option, cadmium-containing jewellery would be allowed to be placed on the EU market, as long as the cadmium concentration/content does not exceed a given level representing a ‘safe’ threshold. This would reduce exposure to cadmium, to a certain level, but individual exposure to consumers cannot be assessed. Because cadmium is a carcinogen for which no safe threshold has been defined and a cumulative toxicant, such a ‘safe’ threshold for exposure through skin exposure does not exist. Therefore, today, it is not defendable from a human health perspective to set a safe level for cadmium in jewellery.

Option J4: Restriction on the migration of cadmium from jewellery articles

Under this option, those placing jewellery articles on the EU market would be required to take all necessary precautions to ensure that the migration of cadmium from such articles does not exceed a stated limit value (normally expressed as a function of time, i.e. release level per week). This would reduce exposure to consumers in general, but individual

exposure to consumers cannot be assessed. To introduce such a measure, it is necessary to have a recognised, standardised method for measuring migration of cadmium from jewellery articles which is not available today. In addition, as described for option J3, there is no agreed 'safe' level of migration below which any adverse effect for the consumer can be confidently excluded from exposure through skin contact.

The enforceability of this option has been questioned by several Member States.

Options J3 and J4 will be discarded for further analysis because there is no 'safe' level of cadmium exposure to consumers and therefore these options are not defendable from a human protection perspective.

4.3 Cadmium in PVC

Option P1: Business as usual

Under the 'business as usual' option the existing limit of 100 ppm on cadmium concentration would continue to apply for those products listed under Annex XVII to the REACH Regulation. However, the placing on the market for example of profiles (including square cable ducts) or roofing containing more than 100 ppm would still be allowed (as these two applications are not covered by the current restriction). This option would exclude the recycling of cadmium containing PVC in products listed under Annex XVII to REACH.

Option P2: Complete restriction on the use of cadmium in PVC placed on the market

Under the current legislation only a few PVC products are restricted. Under this option ***all*** PVC products will become restricted. The key changes compared to the 'business as usual' option introduced under this option would be that new (and recycled) profiles, square cable ducts and roofing would need to meet the 100 ppm cadmium concentration limit. This option corroborates the voluntary action by European industry (Vinyl 2010) not to use cadmium in new PVC products, but it excludes the possibility to recycle of cadmium containing PVC in specific building products.

Option P3: Complete restriction on the use of cadmium in PVC placed on the market with an exemption for certain rigid PVC construction articles[17] only if manufactured with PVC recyclate without an upper concentration limit for cadmium and without time limit

This option introduces a complete restriction on the use of cadmium in PVC products with an exemption for certain rigid construction products, made with recycled PVC, without an upper limit for cadmium or time limit. This option allows mixed rigid PVC waste to be used for recycling into rigid PVC building products, with a concentration of cadmium exceeding 100 ppm, without a specific time limit.

The VITO models (VITO, 2009) show that this level of cadmium in recycled building products will not exceed 1,000 ppm and the level of PVC will drop 100 ppm below 2050.

[17] Profiles for windows, doors, decking, fencing; roof gutters; pipe fittings and middle layers of 3 or more layer pipes with the exception of drinking water pipes; roller shutters; rigid sheets for building applications; cladding or cover); blinds; doors; bottom or intermediate layers of multi-layer flooring; sound proofing walls; cable insulation; cable ducts profiles; pallets, box pallets and other load boards.

Therefore this option is be counterproductive to the ban of the use of cadmium in Europe and the voluntary commitment of industry (Vinyl 2010). The option is therefore discarded from further analysis.

Option P4: Complete restriction on the use of cadmium in PVC placed on the market with a time limited exemption for certain finished rigid PVC construction articles[18] if manufactured with PVC recyclate with higher concentration limits for different article types

This option introduces a complete restriction on the use of cadmium in PVC products with an exemption for certain rigid construction products, made with recycled PVC, with an upper limit of 1,000 ppm for cadmium as well as a specific time limit. This option allows mixed rigid PVC waste to be used for recycling into rigid PVC building products, with a concentration of cadmium up to 1,000 ppm[19], with a specific time limit. At the end of these time-limited derogations, the originally exempt PVC articles, containing recycled PVC would need to meet a 100 ppm cadmium concentration limit.

Option P5: Complete restriction on the use of cadmium in PVC placed on the market with an exemption without a time limit for certain finished rigid PVC construction articles[20] if manufactured with PVC recyclate with higher concentration limits for different article types

This option introduces a complete restriction on the use of cadmium in PVC products with an exemption for certain rigid construction products, made with recycled PVC, with an upper limit of 1,000 ppm[21] for cadmium without a specific time limit. This option allows mixed rigid PVC waste to be used for recycling into rigid PVC building products, with a concentration of cadmium up to 1,000 ppm, without a specific time limit. The calculation of the concentration limit is based on the same principle as for option P4.

Because of the voluntary agreement of the European industry that includes a commitment not to use cadmium in new PVC, the presence of cadmium in recycled PVC is expected to reach a level lower than 100 ppm by 2050. A continuous exemption is therefore not required and could even be counterproductive to the phasing-out of cadmium in PVC in the EU. For this reason option P5 is not considered further in this assessment.

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18 See footnote 17

19 The suggested concentration limit of 1,000 ppm is based on a study (VITO, 2009) which has used information from historic use and the mode developed by the European Converters Industry (EuPC) which predicts the amount of available recyclable waste to show how the concentration of cadmium in profiles, non pressure pipes and round cable ducts made from recycled PVC will develop in the future (Annex IV). The concentration of cadmium in PVC containing recycled material is likely to decline below 100 ppm in 2050.

20 See footnote 17

21 See footnote 19

Summary of options for PVC :

	Use of Cadmium (Cd) in certain PVC products restricted	**Use of Cd in all PVC products restricted**	**Exemption for certain products if manufactured with PVC recyclates**	**Higher Cd conc limit for certain products if manufactured with PVC recyclates**	**Time limited period higher Cd conc limit for certain products if manufactured with PVC recyclates**
P1 Baseline	**X**				
P2		**X**			
P3		**X**	**X**		
P4[22]		**X**		**X**	**X**
P5		**X**		**X**	

Section 5: Analysis of impact

The analysis of the impacts of the various policy options has been conducted taking into account health, environmental and socio-economic impacts.

Details of the calculations of health benefits can be found in Annex V.

5.1 Brazing materials

Option B1: Business as usual (baseline scenario)

DIY and professional users will be able to continue to use brazing sticks, with possible negative impacts on their health as described in section 2.1.1.

This scenario allows specific sectors such as aerospace and defence technology to continue to use cadmium in specific applications for which currently no alternatives exist.

For authorities this scenario will entail continuous enforcement of exposure limits which is associated with certain measurement and inspection costs.

Adverse impacts on the environment will continue because of the release of cadmium during manufacture, disposal and through ventilation systems.

[22] For example P4 means, use of Cd in all PVC products restricted, in certain products higher Cd concentrations allowed for a time limited period

Option B2: The complete restriction on the marketing and use of cadmium-bearing brazing alloys

There will be a positive impact on the health of DIY users, estimated at 0.7 – 2.2 Million Euro (RPA, 2009)[23] over 20 years from a reduction of risk of deaths or disease from exposure to cadmium. Benefits for EU workers are reduction of exposure to cadmium and present value estimates from preventing lung cancer and emphysema are estimated at 98-473 million Euro over 20 years (RPA, 2009)[24.]

For manufacturers no SME impacts are expected, as brazing alloy manufacturer companies are apparently large. Given that cadmium-free alternatives are already available on the market, the overall impact on suppliers is expected to be limited. There could be one-off capital costs for lost investment on machinery estimated at 150.000 Euro, operational costs for promotion material estimated at 12.000 Euro, and costs for disposal, estimated at 3-4.5 million Euro across the EU (RPA, 2009).

The hobby users will have to change habits but enjoyment will only be impacted marginally. Several scenarios have been elaborated (RPA, 2009) on the costs for consumers for alternative alloys, gases and additional heating time and the estimate is 7.8 - 147 million Euro over 20 years[25]. For professional users the cost of alloys increases by 47-201 million Euro over 20 years (RPA, 2009)[26]. The cost of heating alloys only increases marginally (0.5 – 40 Euro/year per user) because cadmium brazing alloys can be used at lower temperatures. Training costs are estimated at 273.6 Euro per employee.

For Member States limited impact is expected as they are familiar with mechanisms for implementing restrictions. Active monitoring on a whole is not expected to increase. The Member States most affected will be the UK, Germany, France, The Netherlands and Belgium (RPA, 2009). Enforcement will only be possible at retail level, i.e. at the distributors of alloys and professional users.

For the environment there will be benefits because of less cadmium fumes and accidental release but they are expected to be small and therefore not quantified within the framework of this impact assessment.

For very specific safety critical applications such as aerospace and defence[27] no alternatives are available for cadmium in brazing alloys which suggests that these applications need to be exempted from possible restrictions.

Professional users and suppliers of brazing alloys for professional use there seem already to be shifting to cadmium free alternatives, which is also in line with draft ISO 17672. ETUC

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23 See Annex V.

24 See Annex V.

25 The scenario is based on 112.500 users, with different user scenarios (intensity, type of gas, type of alloy)

26 The cost of cadmium-bearing brazing alloys sold to professional users ranges between €180 and €380 per kilogram of alloy. Taking into consideration a 20-26% price increase when cadmium-free alloys are used an the estimated alloy consumption by professional users of 90-140 tonnes per year across the EU, the annualised additional cost to professional users per year would be €3.24-13.8 million (Present Value: €47-201 million over 20 years with a discount rate of 4%)

27 In aerospace and defence the use of cadmium-bearing alloys is required for ensuring the integrity of construction and the attainment of require high safety standards

(The European Trade Union Confederation) is in favour of replacing dangerous chemicals where a safer alternative is available and has put cadmium on the priority list for substances for authorisations and restrictions. However, some DIY users and suppliers of brazing materials to DIY users have expressed reluctance to change their way of working because of acquired habits and increase of costs.

Option B3a: Restriction on the use of cadmium-bearing brazing fillers under prescribed conditions for consumer use

This option (prescribing the use of alloys, gases, use fume extractors or working outside) would force DIY users who wish to continue to use cadmium containing brazing fillers to invest a considerable amount for installing fume extractors. The overall investment could range between 1.5 and 7.0 million Euro (one-off) and costs for the filters would be 7.6 million Euro (over 20 yrs), savings may occur from switching to propane heating (RPA, 2009)[28]. For consumers opting to switch to cadmium-free alloys the overall cost is estimated at 3.6-73 million Euro (over 20 yrs)[29].

The positive impact on health of the DIY user will depend on the compliance, however, enforcement will be difficult.

A small benefit can be expected for professional users taking over from DIY. There could be a small loss for oxy-acetylene gas suppliers due to loss of cylinder rental fees (64 million Euro over 20 years) (RPA, 2009) but these will be balanced by increased use of propane gas consumption. There will be an increased revenue from sales from fume extractors to DIY users estimated at 1.5-7.0 million Euro (one-off) and 7.6 million over 20 years for the filters (RPA, 2009).

Enforcement and monitoring by Member States is expected to be difficult because in practice no controls are performed at consumer level.

For the environment there will be benefits because of less cadmium fumes and accidental release but they are expected to be small and therefore not quantified within the framework of this impact assessment. Filters from ventilators will require suitable disposal methods.

5.2 Jewellery

Option J1: Business as usual (Baseline Scenario)

In this scenario there will be continued exposure of children and adults to cadmium through skin exposure and possibly licking and exposure from DIY use. Most affected are young persons as they are the main costumers of costume jewellery.

Imports into the EU from jewellery products with high cadmium content can continue.

Option J2: Complete restriction on cadmium in jewellery articles

Complete restriction offers the best possible protection to public health and workers.

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[28] In this scenario 28,000 (25%) of the DIY users are installing fume extractors

[29] The scenario is based on 56,000 DIY users with different user scenarios for alloys, gasses and heating time.

The estimated benefits for consumers have been calculated only for adults exposed to high migration rates, based on an age standardised lifetime risk for 'non-cardiovascular cause' deaths (at 3.67-7.22 million Euro over 20 years). Benefits to children, who are a key and at the same time most vulnerable consumer group using costume jewellery, as well as to the environment could not be quantified (RPA, 2009). It is however known that jewellery, and especially costume jewellery is getting more and more popular with young children and teens aged between 13 and 19 years old. That particular age group currently exceeds 80 million across the EU-27 and although not all will be wearing jewellery the potential exposure could be quite substantial.

A significant benefit may occur to 3rd country workers and environment from reduction of possibly unsafe practice in extracting cadmium from waste and during the process of jewellery making.

With regard to EU-based jewellery manufacturers, which are typically SMEs (section 2.1.2) it is unlikely that they would be seriously impacted by a restriction on the marketing of cadmium-containing jewellery as the metal finds limited use within the EU. For EU precious jewellery manufacturers there could be some costs from the use of cadmium free electroforming solders (9.8 – 20 million Euro over 20 years) (RPA, 2009).

For EU costume jewellery manufacturers current use of cadmium is low and therefore costs are estimated below 1 million Euro over 20 years for change of solders and training of workers (RPA, 2009).

Impacts on SMEs would be most likely to arise among importers/suppliers and retailers of jewellery, especially costume jewellery, many of which are small and micro-companies. Ensuring quality control along the supply chain could be difficult and costly for SMEs, especially if their position is at the end of a potentially long supply chain.

Costs related to the analysis of jewellery samples are expected to be 0.01 Euro per individual article of custom jewellery (batch certificates) and 16-40 Euro for individual certificates for precious jewellery. For customers of precious jewellery there may be a small price increase but it will protect them from the malpractice of diluting precious metals. Some costume jewellery products may disappear or become more costly which will have an impact on those with less spending power (young persons/children). SMEs selling costume jewellery will need to adjust to the changes but are expected to do so anyhow on a regular basis because of the fashion dependant nature of these products. Positive for the consumer is that they will be reassured to buy a safe and non-fraudulent product, and specifically for precious jewellery the consumer is expected to be willing to pay the price.

For public authorities additional testing will be needed but cadmium is often tested in any case within the group of heavy metals.

There will be a significant impact on non-EU manufacturers of jewellery due to increased costs of materials and quality control. If non-EU companies would like to continue imports in the EU they will need to stop using cadmium and make the proper investments. For these companies, no calculations of benefits are available, but a complete restriction will give incentives to non-EU businesses (jewellery manufacturers) to improve practices and better protect workers' health and the environment. There are for example more than 100,000 manufacturing units in India, employing mostly up to 10 persons each. The extent to which these benefits would be achieved may however depend on the extent to which the EU

jewellery market is important to non-EU jewellery manufacturers and on the willingness of producers in non-EU countries to adjust their processes to the requirements of EU legislation.

For the environment the restriction of cadmium will reduce disposal, release from recycling and jewellery making as well as accidental release.

The implementation would imply control and market surveillance activities by enforcement authorities, similar as for other existing restrictions of chemicals in consumer products.

Limited input has been received from the EU-based jewellery trade associations or companies as a result of the apparent limited use of cadmium in jewellery making. Concerns were expressed by a small number of companies involved in costume (pewter) jewellery fearing that a ban might affect their ability to purchase and use pewter jewellery containing small levels of the metal.

Limited information has been received from non-EU trade associations and their reactions depended on whether they believed that the restriction would affect positively or negatively their exports into the EU.

Amongst the suppliers of alloys some did not express a direct objection were others feared that the lack of similar priced alternatives for soldering could have negative impacts on the EU jewellery industry.

5.3 PVC

Option P1: Business as usual (Baseline scenario)

The main issue under this option is that, whilst PVC recycling activities in the EU are expanding, the presence of cadmium in post-consumer profile waste and consequently in mixed rigid waste places an obstacle to the use of this recyclate in the manufacture of pipes and round cable ducts for which a cadmium content limit of 100 ppm currently applies. The limit of 100 ppm in these and other building products limits the choice of the converters to using virgin PVC. The decreased demand, increased administrative burden and higher costs for quality control will have a negative impact on waste recyclers which are mostly SMEs. Waste collectors will see a decreased demand for PVC waste and increase disposal.

Exposure to workers during recycling (grinding) has been measured in 2005 on behalf of Recovinyl in 5 factories in Europe and found to be below 2% of the maximum exposure limit.

Lower levels of recycling mean increased landfilling/incineration which has a negative impact on the environment (especially through the release of CO_2) and the recycling industry.

Option P2: Complete restriction on the use of cadmium in PVC placed on the market

This option represents a complete restriction of cadmium in PVC placed on the market to 100 ppm. It will reduce the level of cadmium in all articles made from new PVC, prevent imports of cadmium containing PVC into the EU, but will result in an overall reduction of recycling of Cadmium containing PVC articles. The latter has a negative impact on the recycling business and the environment.

For landfills and incinerators there would be an increase of demand. Producers of PVC products will have to use virgin PVC which has a higher cost than recycled material, which will have a negative impact on producers of window frames and square cable ducts but has no significant effect of producers of flexible roofings as the 100 ppm limit will not be surpassed in new roofings containing recyclate. In total, for the period of 2010-2050 the financial impact for the PVC profile industry is estimated to 1,197-1,227 million Euro extra costs[30] . Countries that currently recycle (Western Europe) will be more affected than countries with lower recycling rates (Eastern and Southern Europe). There will be a negative impact on the employment in recycling, estimated up to a loss of 9.200 person years in employment (2010-2050) (VITO, 2009) but a small positive one in the incineration/landfill sector.

There is a negative impact on the environment due to the increased landfill and incineration, with an expected increase of release of CO_2 emissions of 7.2 million tonnes (VITO, 2009).

Option P4: Complete restriction on the use of cadmium in PVC placed on the market with a time limited exemption for certain finished rigid PVC construction articles[31] if manufactured with PVC recyclate with higher concentration limits for different article types

This option allows to use cadmium in certain specific PVC products (building products containing recycled PVC), with a certain concentration and time limit. The option acknowledges the efforts of the European PVC industry which has voluntarily eliminated the use of cadmium stabilisers in PVC and also restricts imports of not recycled cadmium containing PVC into the EU.

According to VITO (VITO, 2009), the voluntary commitment of the EU PVC industry to phase all cadmium in PVC is likely to result in a decline to 100 ppm of cadmium in profiles in 2050 with intermediate concentrations below 200 ppm by 2035, 400 ppm by 2025 and 800 ppm by 2015. For pipes, under this scenario 100 ppm is likely to be reached by 2040, with intermediate concentrations below 200 ppm by 2030, 400 ppm by 2020 and 800 ppm by 2015.

VITO estimates that the total profit from allowing cadmium to be present in recycled non-pressure pipes, for recyclers and converters, is between 2,312 – 2,783[32] million Euro, creating 7,095 additional person years of employment (for 2010-2050)[33] (VITO, 2009).

Recycling would save costs of landfilling/incineration estimated to 3,14 million tonnes, representing savings up to 314 million Euro for the period of 2010-2050 (VITO, 2009).

For pipe manufacturers there could be a single-off cost of 0.5 million Euro for converting each single production line to co-extrusion, which amounts to a total of 50 million Euro for the estimated total of 100 extruders. (RPA, 2009).

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30 The assumptions are based on changes in turn-over for the recycling and converting industry, impact on employment and the global warming potential (expressed as tonnes of CO_2) (VITO, 2009) http://www.vinyl2010.org/images/stories/final%20report%20vito%20study%20on%20cadmium%20in%20pvc%20recyclate.pdf

31 See footnote 30

32 See footnote 30

33 See footnote 30

The turnover loss for virgin PVC producers will be small compared with the total turnover of the virgin PVC industry. The absence of the need to monitor cadmium would reduce the administrative burden for companies and Member States can decrease market surveillance. Recycling activities associated with non-pressure pipes and round cable duct manufacturing would expand in the EU.

Landfill and incineration will be reduced which has a positive impact on health and the environment, the estimated reduction of CO_2 release is 6 million tonnes (for 2010 – 2050) (VITO, 2009). An assessment of the contribution of accidental release of cadmium to the environment from fires has not been possible as high levels of heavy metals will also be released from other sources such as IT equipment or other waste materials.

In order to work towards an effective phase-out it is necessary to monitor the presence of cadmium in building products containing recycled PVC and to update the legislation accordingly.

The EU PVC industry is keen to continue using PVC recyclate. The limit of 1,000 ppm was often perceived as an acceptable solution although some companies expressed concern on the whether the limit and timeframe could be met.

Section 6: Comparing the options

6.1 Brazing materials

Comparison of Effectiveness and Efficiency		
Policy Option	Effectiveness	Efficiency
B1 – Business as usual	**Neutral**: Does not meet the objective of human health and environmental protection.	**Neutral**: No additional resources needed, but objectives are not reached.
B2 – complete restriction for consumer and professional use	**High:** It meets the objective of human health protection for DIY and professional users. It protects the public and environment from exposure to cadmium as a result of brazing operations.	**High:** Expected health benefits for users and consumers exceed costs, but costs are significant.
B3a – use by consumers under prescribed conditions	**Medium:** Meets the policy objective for DIY users only. However, there are doubts on the possibilities to enforce.	**Medium:** Possible high costs to consumers, depending on the type of user. Positive human health and environmental impacts.

6.1.1 Preferred Option for brazing materials

The option B2 to restrict completely the use of cadmium-bearing alloys for both consumer (DIY) and professional users is estimated to be the most beneficial. Many distributors are selling brazing alloys both to consumers and professional users, therefore a restriction of the sale to both user categories will prevent problems of distinguishing between them and facilitate enforcement and control.

A complete restriction on the DIY uses of cadmium-bearing alloys would eliminate exposure to carcinogenic cadmium oxide fumes, especially given the current conditions of use including garages without ventilation and inappropriate torches.

Professional users are expected to use higher quantities of cadmium containing alloys than consumers. A restriction would result in an increased alloy cost of 20%, marginally prolonged brazing periods, need for higher temperatures and need to change old habits but there has been a trend among professional users since the 1970s to steer clear of cadmium-bearing alloys and many users have now successfully abandoned cadmium.

For consumers, the monetised benefits from preventing deaths due to increased cadmium levels (0.7-2.2 million Euro over 20 years) could be smaller than the estimated cost from changes in the cost of alloys and heating requirements (7.8-147 million Euro over 20 years, this estimate has a large range because of the uncertainty of the price of the alloys, the variation in gas use and time of heating). But considering expected benefits from preventing short-term exposure to high concentrations of cadmium oxide (that could not be monetised because it was disproportionate to quantify) a total restriction is considered as beneficial on a whole. For professional users, the estimated benefits from preventing lung cancers and emphysemas (98-473 million Euro over 20 years) appear to exceed the projected costs to industry (50-205 million Euro over 20 years including training costs and one-off costs of manufacturers of alloys) from a restriction.

The benefit to the environment benefits from preventing the release of cadmium to the environment, which could be as high as 0.7 t/y across the EU (RPA, 2009).

For some specific uses a full restriction is not appropriate as alternatives are currently not available. In aerospace and defence the use of cadmium-bearing alloys is required not only for ensuring the competitiveness of EU businesses but also for ensuring the integrity of construction and the attainment of required high safety standards. Also, in safety-critical applications (e.g. anti-corrosion parts of turbines), cadmium-bearing alloys are the fillers of choice.

In several of the identified sectors the presence of SMEs is expected to be significant with a considerable number of one-man or family companies being present. The impacts on SMEs would be both substantive (created by the obligation to adapt the nature of their product/services to meet the new requirements which would mean increased alloy costs for professional users) and administrative (SME suppliers would need to provide to their customers information on alternative brazing alloys). The most significant impact would probably arise for professional users of cadmium-bearing alloys, i.e. those who have still not switched to alternatives. At the same time, the costs of providing adequate protection to employees could decrease due to the elimination of exposure to cadmium.

A **restriction on all uses of cadmium in brazing alloys for consumer and professional use accompanied by a derogation allowing continued use for safety-critical and**

aerospace/defence applications is therefore proposed in Annex XVII of the REACH Regulation.

6.2 Jewellery

Comparison of Effectiveness and Efficiency of Selected Policy Options		
Policy Option	Effectiveness	Efficiency
J1 – Business as usual	**Neutral:** It cannot meet the objective of human health protection.	**Neutral:** No additional resources needed but objectives are not reached.
J2 – Complete restriction on cadmium in jewellery articles	**High:** It meets the objective of human health protection.	**High:** Positive human health impacts and environmental impacts. The health benefits are expected to outweigh the costs taken into account that positive health effects for the vulnerable children group could not be quantified.

6.2.1 Preferred Option for jewellery

Option J2, the complete restriction on the use of cadmium in jewellery is considered to be the best option. Cadmium is a carcinogen and consumers should be protected against the exposure coming from jewellery articles containing cadmium. These products may currently enter the EU market without any monitoring or control and policy options other than a restriction are currently not suitable to control the risks.

Estimated benefits in relation to adults with high exposure through jewellery are €1.47-2.20 million for the age standardised lifetime risk based on the 'all causes' death rate estimates for the EU-15 population. This rises to a maximum of 3.67-7.22 Euro million for the age standardised lifetime risk based on 'non-cardiovascular cause' deaths in the EU-27 (over 20 years). The estimated benefits appear, at first sight, to be modest in comparison to the likely costs to the EU economy but they do not include benefits to children. Because of a lack of data it would have been disproportionate to quantify benefits to children, but they present the key and at the same time most vulnerable consumer group using costume jewellery and their high vulnerability to toxic chemical exposure is recognised. In addition, a ban of cadmium in jewellery will raise consumer protection standards in the EU, as consumers are often not aware when buying jewellery looking like gold or silver that they may in fact acquire an article containing potentially harmful quantities of cadmium. There will also be a significant benefit to 3rd countries workers and environment from the reduction of possibly unsafe practice in extracting cadmium from waste and from the process of jewellery making.

In the EU this measure will have an impact on the 22,500 companies making precious jewellery, employing around 94,000 people and on the 5,350 companies making costume jewellery, employing around 20,000 people.(CBI, 2008) The estimated costs involved with this preferred option for the EU jewellery industry, estimated at 9.8 – 20 million Euro over 20 years.

The biggest impact of this option will be on the manufacturers and environment outside the EU. The benefits could not be quantified but a complete restriction will give an incentive to non-EU businesses (jewellery manufacturers) to improve practices and better protect workers' health and the environment. The extent to which these benefits would be achieved may however depend on the extent to which the EU jewellery market is important to non-EU jewellery manufacturers and on the willingness of producers in non-EU countries to adjust their processes to the requirements of EU legislation. Third country SMEs will have to adjust to the EU requirements, meaning they will need to work with cadmium free starting material which will have some extra costs for the primary materials and requirements for quality control.

Impacts on SMEs would most likely arise among importers/suppliers and retailers of jewellery, especially costume jewellery, many of which are small and micro-companies. The main additional burden on these companies would be the additional cost of cadmium-free jewellery and particularly the costs of meeting the requirements on the safety of the articles they place on the market. SMEs will need to ensure that there is quality control along the supply chain. This could be difficult if their position is at the end of a potentially long supply chain.

In summary, the preferred option for immediate action would be the adoption of a total restriction on cadmium in jewelleries to be included in Annex XVII of REACH.

6.3 PVC

Comparison of Effectiveness and Efficiency Selected Policy Options		
Policy Option	Effectiveness	Efficiency
P1 – Business as usual	**Neutral:** Maintenance of the status quo of human health and environment protection in the frame of scope of existing (limited) restrictions. Risk by discontinuing the use of PVC waste recyclate with negative environmental impacts For products currently exempted: no effect.	**Neutral:** Increased landfilling and incinerating for products that could be used for recycling have a negative impact on the environment and industry. Could have a negative impact on the Vinyl 2010 voluntary agreement and imports of PVC containing cadmium can continue.
P2 – complete restriction of cadmium in PVC	**Low:** Negative environmental impacts because of an increase of landfill and incineration.	**Low:** Increased landfilling and incinerating for products instead of recycling would have a negative impact on the environment and industry
P4 –restriction with a time limited higher Cd concentration level for certain building articles if manufactured with PVC recyclate	**High:** Prevent breaching of existing legislation. Supports phasing-out of cadmium	**High:** Significant positive environmental impact as landfilling/incineration would be avoided. Positive impact on industry as it supports voluntary action Vinyl 2010

6.3.1 Preferred Option for PVC

The preferred option (P4) is to temporarily raise the limit of cadmium in certain specific building products in order to allow the use of post-consumer profile waste in the manufacture of new articles. The complete restriction of cadmium in all PVC products would have a negative impact on the environment and recycling efforts, whereas allowing a higher threshold for building products containing recycled PVC without a time limit does not work towards complete ban of cadmium in the future. Therefore, in line with the basic waste management principles of the European Union, option 4 is preferred.

The relevant scientific literature shows that stabilisers are rather fixed in the PVC matrix. Studies have shown that the migration rate and mobility of heavy metal stabilisers from PVC

is low[34]. Nevertheless, the possibility of migration of cadmium from PVC should not be totally neglected. Therefore, in order to minimise the risk of release from some articles with potential direct consumer or environmental exposure, recycled material containing cadmium in those articles shall only be used in such a way that there is negligible release of cadmium form the recycled product to consumers or the environment. In practice this means that in certain critical articles, such as pipes, recycled PVC shall only be used in internal layers, not directly in contact with consumers or the environment.

The cadmium concentrations in PVC waste and consequently in non-pressure pipes and round cable ducts made from recycled PVC will not remain static and are expected to rise for a number of years but will subsequently decline and eventually fall below 100 ppm (beyond 2040-2050 according to the model – Annex IV). Therefore, it would be prudent to increase the cadmium content limit for building products and for a limited period only, after which an evaluation could be undertaken to establish more conclusively the presence of cadmium in waste and in finished articles.

On the basis of the calculations of the VITO report (2009), a limit around 1,000 ppm would allow the use of cadmium-containing recyclate while substantially reducing the possibility of accidental breaches of the regulatory cadmium content limit. The models (Annex IV) show that the concentration is likely to decline towards 500 ppm within 10 years. Therefore, a revision of the limit is envisaged within this timeframe, with a view to reduce the limit, based on real time monitoring.

There is no evidence that SMEs would be disadvantaged under the preferred policy option. Therefore, we do not believe that any mitigation measures aimed at SMEs are needed. Many companies in the recycling sector are SMEs and these will to a large extend benefit from the implementation of the preferred option.

[34] ARGUS (2000), The Behaviour of PVC in Landfill, pp. 24 - 26

In summary, the preferred option is to extend the existing limit of 100 ppm cadmium to <u>all</u> PVC articles and to allow that the limit is raised to 1,000 ppm for a period of 10 years, for the following list of building products[35], if manufactured with PVC recyclate and provided that the migration of cadmium from these products into the environment is negligible:

– profiles for windows, doors, decking, fencing

– roof gutters

– pipe fittings and inner layers of pipes, with the exception of drinking water pipes

– roller shutters

– rigid sheets for building applications (cladding or cover)

– blinds

– doors

– bottom or intermediate layers of multi-layer flooring

– sound proofing walls

– cable insulation

– cable ducts profiles

– pallets, box pallets and other load boards

Following "real life monitoring" of cadmium concentrations in representative samples of waste, recyclate and final articles manufactured with recyclate the exemption shall be revised, with a view to reduce the limit, after a timeframe of 10 years.

[35] For rigid roofing calculations have shown that the cadmium content in new products containing recycled PVC does not exceed 100ppm. There is therefore no need to add this product to the exception list.

6.4 Summary of cost-benefits of options

Option	Cost	Benefit	Remark
Brazing – restriction of Cadmium Preferred option	57.8 – 352 M€ over 20 years (gas, heating)	99.3 – 475 M€ over 20 years (health – long term exposure)	Costs do not include training costs one-off costs of alloy manufacture Benefits to short term exposure co not be included due to the absence quantitative data
Brazing – use by consumers under controlled conditions	11.2 – 81 M€ over 20 years (filters and cadmium free alloys) 1,5 – 7 M€ one off for fume extractors	0.7 – 2.2 M€ over 20 years (health)	
Jewellery – complete restriction on cadmium Preferred option	9.8 – 20 M€ over 20 years (precious jewellery) Below 1 M€ over 20 years (EU costume jewellery manufacturers)	3.67 – 7.22 M€ over 20 years (health of adults)	Benefits for children could not be quantified due to absence of data, although children represent the mo vulnerable, and in the case of cost jewellery the most important, consumer group Figures do not include costs for importing SMEs Figures do not include costs and benefits for third county companie
PVC – complete restriction on cadmium	1,200 M€ (loss in turn-over in recycling, employment and global warming) 9,200 person years 7.2 M Tonnes CO_2		Estimates over 40 years from 2010 2050
PVC – complete restriction on cadmium with exemptions for recycling in building products Preferred option	50 M€ one off costs for extruders (100 extruders)	2,312 – 2,783 M€ (turn-over in recycling, employment and global warming) 7,095 person years 6.0 M Tonnes CO_2 314 M € (savings landfill)	Estimates over 40 years from 2010 2050

Section 7: Monitoring and evaluation

The monitoring and enforcement of restrictions concerning cadmium will be undertaken by the national authorities currently responsible for the enforcement of REACH and in particular the authorities in charge of consumer protection and enforcement of environment legislation in each Member State.

The REACH Regulation (EC) No 1907/2006 (REACH Regulation) has established a European Chemical Agency for the purposes of managing and carrying out technical, scientific and administrative aspects of the Regulation and to ensure consistency at Community level in relation to these aspects.

In particular a Forum for Exchange of Information on Enforcement managed by the Agency has been set up to coordinate the action of Member States authorities responsible for enforcement of REACH.

In addition, Regulation EC No 765/2008 concerning accreditation and market surveillance is describing in details the obligations of Member States concerning market surveillance such as to perform checks of products on an adequate scale, and take restrictive measures such as withdrawals from the market.

For the enforcement of the restrictions on Cadmium, the burden on the National Authorities will be similar as for restrictions in other areas. As it is the case for other consumer articles regulated under REACH, Member States will notify dangerous products under the "Rapid Alert System for non-food consumer products" (RAPEX).

An evaluation of the measures concerning cadmium in PVC is envisaged after 10 years with a view to reduce the limit, based on real time monitoring.

Section 8: References

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Annex I: Glossary

DIY: Do-it-yourself

ECVM: The European Council of Vinyl Manufacturers www.ecvm.org

EFSA: European Food Safety Authority

EuPC: European Plastics Converters

ISO: International Organisation for Standardisation

OEL: Occupational Exposure Limit

PPE: Personal Protection Equipment

PVC: Polyvinyl chloride

REACH: the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1st June 2007. It streamlines and improves the former legislative framework on chemicals of the EU (European Parliament and Council Regulation (EC) No 1907/2006).

SCTEE: The Scientific Committee on Toxicity, Ecotoxicity and the Environment

Vinyl 2010: voluntary commitment, in which the PVC industry committed itself not to use cadmium as stabiliser in PVC after 2001 http://www.vinyl2010.org

STEL: Short Term Exposure Limit

Annex II: Stakeholders consultation by RPA

OVERVIEW OF CONSULTATION UNDERTAKEN BY RPA FOR THE IMPACT ASSESSMENT FOR CADMIUM

1. CONSULTATION WITH THE CADMIUM PRODUCING INDUSTRY

1.1.1. Overview of Consultees

The following table summarises the categories of consultees contacted for the purposes of the impact assessment and the number of organisations contacted directly[36]. The third column from the left indicates the organisations/persons with whom communication was established (i.e. some input, even a negative one, was received).

Table 1: Overview of Consultation on Cadmium Production in the EU			
Category of consultees	Number contacted	Number of responses	Locations
Producers of cadmium and cadmium oxide	4	4	BE, DE, NL, NO
Associations of producers of cadmium	1	1	INTL
Totals	5	5	

1.1.2. Forms of Consultation

The consultation with the **Cd/CdO producers** took the form of email communication, without the use of a dedicated questionnaire. The companies were asked to:

- *confirm production tonnage data collected from literature; and*
- *provide the most up to date tonnages on primary and secondary production of Cd and CdO in the EU.*

The inputs of the companies were subsequently co-ordinated by the **International Cadmium Association**. The Association was also asked by the consultants to provide an updated version of the Cd mass flow chart presented in the EU RAR. This was made available in July 2009.

[36] For instance, contact has been made with trade associations. It is possible that emails or questionnaires sent to associations were further forwarded to member companies; therefore, the numbers given in this paper may not represent the actual number of organisations contacted.

1.1.3. Views of Consultees on the Proposed Policy Options

We did not receive specific views on the detailed proposals for policy action presented in the impact assessment report.

2. CONSULTATION ON BRAZING

2.1.1. Overview of Consultees

The following table summarises the categories of consultees contacted in the wider EU brazing industry for the purposes of the impact assessment and the number of responses received.

Table 2: Overview of Consultation on Cadmium in Brazing in the EU			
Category of consultees	Number contacted	Number of responses	Locations
Manufacturers and suppliers of brazing alloys	37	16	BE, CZ, DK, FR, DE, HU, IT, NL, PL, PT, SI, ES, CH, UK
Manufacturers and suppliers of soft solders	7	5	CZ, DK, UK
Suppliers of materials to model engineers	4	1	UK
Professional manufacturers of model boilers	12	3	UK
DIY model engineers*	19	19	BE, DK, FR, MY, NL, CH, UK
DIY model engineer associations/clubs	29	8	AU, BE, FI, FR, DE, IE, NL, SI, UK
Experts on pressure equipment regulations	2	1	UK
Companies-professional users of brazing materials	51	7	FR, DE, IT, SE, UK
Associations representing professional users of brazing materials	23	12	EU, CZ, UK
Suppliers of ventilation systems	7	2	DK, UK
Suppliers of PPE	1	1	UK

Table 2: Overview of Consultation on Cadmium in Brazing in the EU			
Category of consultees	Number contacted	Number of responses	Locations
Totals	192	75	
Notes: * Contacts with several others made through online discussion forums			

2.1.2. Forms of Consultation

The main form of consultation used in the preparation of the impact assessment was email communication, although telephone interviews as well as a face to face meeting were arranged.

A questionnaire was prepared at the onset of the study aimed at collecting information from those **companies manufacturing and supplying brazing alloys in the EU**. This questionnaire was agreed with DG Enterprise and Industry and was placed on the Commission Internet site. In summary, the questions asked included:

- *questions on the tonnages of brazing alloys manufactured and supplied to EU professional and DIY users over the last 5 years, including past and envisaged future trends;*
- *questions on the size and structure of companies' supply chains in the EU;*
- *questions on the list of professional and DIY applications in which cadmium-bearing brazing alloys may be used and the size (in tonnage and € terms) of the associated market segments;*
- *questions on the technical conditions under which cadmium-bearing brazing alloys may be used safely and effectively,*
- *questions on the availability, technical suitability and relative cost of alternative brazing alloys; and*
- *questions on consultees' views on a range of policy options.*

This questionnaire was sent out to many brazing alloy manufacturers and suppliers electronically. This was followed up by reminder emails, when no response was forthcoming[37]. Telephone conversations were also held were additional information or clarification was required as well as site visit to meet with a leading supplier of brazing alloys.

[37] This approach of sending reminders was generally followed for all cadmium applications.

With regard to **users of brazing alloys**, they were approached by email as well as through online discussion boards dedicated to model engineering. Our emails contained a short list of questions which were further followed by subsequent emails and telephone conversations, as necessary. Questions extended to **DIY users** included:

- *Do you use cadmium-bearing brazing filler materials? If yes,*
    - *in what capacity (professional user or DIY user);*
    - *for how many years;*
    - *what is the average quantity of Cd-bearing filler you use (in grams per year);*
    - *what is the maximum quantity of Cd-bearing filler you have used in the past, if your consumptions has declined in recent years (in grams per year);*
    - *what is the maximum quantity used per single application (i.e. during one day of use);*
    - *where/whom do you purchase these materials from?*
- *In which applications do you use cadmium-bearing materials? Please provide details.*
- *What is the form in which these cadmium-bearing materials are used (sticks, wires, strip, powder, paste)? Is form an important consideration and why (for instance, are there specific tasks that cannot be performed with certain forms)?*
- *When you use these materials, what type of heating source is employed (for instance, a propane torch)?*
- *Do you normally monitor the working temperature? If yes, by what means? How can you ensure that overheating of the cadmium in the filler does not occur?*
- *On average, how long do you spend brazing with cadmium-bearing materials? Please indicate how often you do it (an example answer: "once a week, for 15 minutes per single application").*
- *In which location are these activities conducted (in a workshop, garage, cellar, spare room, etc.)?*
- *When using brazing materials, do you usually use any ventilation or personal protective equipment (e.g. a mask) or perhaps a physical barrier (for instance, protecting yourself behind a glass surface)?*
- *Have you ever had any symptoms of 'metal fume fever' when working with these materials?*
- *If there have been incidents during which you have felt unwell, what action did you take and what was the outcome?*

- *Have you received advice on the maximum length of time that you should undertake brazing activities (e.g. no more than 15 minutes at a time, no longer than 1 hour a day)? Have you received any advice on the use of ventilation/personal protective equipment, etc.? If you have answered 'yes' to either of these questions, please specify the type of advice received and from whom.*

- *Are you aware of alternative brazing materials that do not contain cadmium? If yes, have you used them in the past?*

- *If you have used alternative brazing materials in the past, can you indicate whether they perform as well as cadmium-bearing brazing materials? Are they more or less costly compared to cadmium-bearing brazing materials?*

- *Do you think there are any specific tasks/applications for which alternatives are unsuitable and, if so, what and why?*

Of interest is also communication with an Australian model engineering association on whether there have been any catastrophic accidents associated with the use of alternative brazing alloys in Australia and New Zealand, as suggested by certain users of online discussion boards.

With regard to **professional users**, these are mostly approached by email through European industry associations (although separate emails where sent to individual companies too). Questions sent to such associations included the following:

- *Please describe in which applications within your industry sector cadmium-bearing brazing alloys (silver solders) are used. Please provide as much detail as possible.*

- *Is there any particular piece of EU-wide or national legislation that has affected the use of cadmium-bearing alloys in your industry sector (examples might include the RoHS and ELV Directives)? Please indicate which specific applications have been impacted and explain whether you expect further impacts in the future.*

- *Can you estimate the number of EU workers that may currently be using cadmium-bearing alloys in the applications you have identified under Question 1? Can you explain in which EU countries the use of cadmium-bearing alloys in these applications is most common? Or, is use likely to take place in all countries?*

- *Would you be able to provide an estimate of the tonnage of cadmium-bearing alloys used in the EU in the applications you have identified under Question 1? If such an estimate is not possible, could you please provide an estimate of the quantity of cadmium-bearing alloy that an average individual user may use in a year and/or an average 8-hour working day?*

- *Can you indicate the duration that a worker might be actively engaged in using (i.e. heating of/exposed to fumes from) the solder in each shift?*

- *What measures are usually taken by users in your industry sector to prevent exposure to cadmium oxide fumes during the heating of alloys? Please provide as much detail as possible, including the technical measures (ventilation, extraction) and personal protective equipment used.*

- *Do you know whether any measurements of exposure to cadmium (workplace or worker) from the use of brazing alloys have been undertaken within your industry sector in the past? If yes, please provide details.*

- *Do you consider that cadmium-bearing alloys are critical for undertaking any of the applications of relevance to your industry sector? Are there applications that would be particularly threatened by a ban on cadmium in brazing alloys (for instance, because alternative alloys are technically inferior)? Please provide details.*

- *We have identified 2 possible options for risk management: (a) a complete ban on the use of cadmium in brazing alloys and (b) a restriction limiting the use of cadmium-bearing alloys to a certain amount (in grams per year) and under strict ventilation conditions. Please help us establish the positive and negative impacts from either of these options.*

Other important sources of information included:

- **companies supplying ventilation systems** – the key questions to them referred to the types ventilation systems that could be used by professional brazers as well as DIY users, their size and air removal capacity as well as their cost;

- **companies supplying pressurised gases** – the key questions to them related to the requirements of the Pressure Equipment Directive and how this piece of legislation may affect the choice of brazing alloys;

- **a leading supplier of PPE** – the key questions related to the availability, technical characteristics and limitations of PPE for brazers; and

- **a number of DIY (copper and steel) boiler inspectors** – the key questions to them included questions on the regulations or codes of conduct that a boiler inspector needs to adhere to, the role of the Pressure Equipment Directive, the frequency and nature of boiler inspections, and any experience with boilers failing tests as a result of the use of cadmium-free brazing alloys.

2.1.3. Views of Consultees on the Proposed Policy Options

For reasons of confidentiality, we cannot provide a detailed account of the views of different consultees regarding the policy options considered and eventually proposed in the impact assessment report. The following should be considered as a general commentary[38]:

- there have been mixed reactions among the manufacturers and suppliers of brazing alloys to the prospect of an EU-wide restriction. As noted in the impact assessment report, two companies with a significant share of the EU market were in the process of withdrawing from the market or moving their customers (largely professional users) to cadmium-free alternatives. However, a small supplier with a large customer base among DIY users in the UK was very keen to continue supplying cadmium-bearing alloys, therefore, was not prepared to subscribe to an EU-wide restriction;

[38] Please note that different arguments that have been made by stakeholders during consultation have been taken into consideration in the preparation of the impact assessment and where these were considered to be important have been presented throughout the impact assessment report.

- among DIY users, again, there was a mixed reaction. The majority of individuals we spoke to would appear to prefer to be able to continue using cadmium-bearing alloys. Some of them had not tried using alternatives and their knowledge of them was rather second-hand. It is notable that among those who appeared to prefer cadmium-bearing alloys, some acknowledged that a switch to alternative is more difficult due to long-acquired habits. Moreover, some users expressed surprise that a restriction was being considered as very few of them had been aware of themselves or any other fellow model engineer ever suffering ill-health from exposure to cadmium fumes. Still there were several users who had successfully used alternatives and would be OK with an EU-wide restriction. An issue highlighted by most users was the need for longer heating times and the likely increase in the cost of brazing alloys once cadmium was restricted; and

- there has been limited input from professional users, perhaps an indication that the majority of them has moved to alternatives. Again, the views of consultees were mixed with some wishing to be able to use cadmium-bearing alloys while other explaining that they have been able to move to alternatives without major issues. Of interest was the testimony of a plumber with working experience in France and the UK who suggested that he had no option but to use cadmium-bearing alloys as the French national regulations (on gas tube fitting) required him to do so.

3. CONSULTATION ON JEWELLERY

3.1.1. Overview of Consultees

The following table summarises the categories of consultees contacted in the wider EU and international jewellery industry for the purposes of the impact assessment and the number of responses received.

Table 3: Overview of Consultation on Cadmium in Jewellery in the EU

Category of consultees	Number contacted	Number of responses	Locations
Suppliers of alloys and precious metal bullion	38	15	AT, BE, CZ, DE, IT, SK, CH, UK
Precious metal refiners	10	1	AT, DE, IT, NL, CH
Companies manufacturing and supplying jewellery articles	126	13	INTL, BE, CZ, DK, FI, FR, DE, HU, IE, IT, NL, ES, SE, UK, USA
Non-EU manufacturers and suppliers of jewellery articles	14	0	BD, HK, PH, VN
Suppliers of electroforming systems and related experts	4	3	FR, DE, UK
Manufacturers of XRF	1	1	UK

Table 3: Overview of Consultation on Cadmium in Jewellery in the EU			
Category of consultees	Number contacted	Number of responses	Locations
scanning equipment			
European associations of jewellery manufacturers and retailers	37	8	EU, INTL, AT, BE, CZ, DK, FI, FR, DE, EL, IT, LT, NL, NO, PT, UK
European associations of fashion jewellery manufacturers and retailers	5	2	EU, CZ, FR, IT, ES
Non-EU trade associations and chambers of commerce (including a small number of EU embassies and University experts)	63	19	AE, BD, BR, CN, HK, ID, IL, IN, KR, LK, MU, MP, PH, RU, SG, TR, TH, US, VN, ZA
Association of Chambers of Commerce	1	1	EU
Trading standards authorities and RAPEX contact points	29	6	AT, BE, BG, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, ES, SE, UK
EU Delegations in non-EU countries	24	20	BD, BR, CN, HK, IN, ID, IL, JP, KR, MA, MX, MO, PH, RU, SA, SG, SL, TH, TU, TR, TW, US, VN, ZA
Hallmarking associations	1	1	INTL
EU Assay Offices and other experts	25	15	AT, CY, CZ, FI, DE, HU, IE, LV, LT, NL, NO, PL, PT, SI, ES, SE, CH, UK
Education establishments (jewellery making courses)	11	2	UK
Totals	389	107	

3.1.2. Forms of Consultation

As for the brazing industry, the main forms of communications were emails and telephone discussions. Two questionnaires were initially prepared and placed on the Commission website, one for **trade associations and companies active in the manufacture and retailing of jewellery articles** and one for **jewellery technology experts**. The key questions asked in these questionnaires included:

- *whether cadmium can be found in jewellery articles (solders, base alloys, electroforming materials);*
- *whether cadmium-containing materials are used in specific countries;*
- *levels of consumption and imports of cadmium-containing jewellery articles;*
- *what the typical levels of prices of cadmium-containing jewellery articles typically are;*
- *what the size of jewellery markets in specific countries is;*
- *what the current testing requirements and techniques in different countries are;*
- *questions on the availability, technical suitability and relative cost of alternative brazing alloys; and*
- *questions on consultees' views on a range of policy options.*

Later in the study, when the importance of cadmium presence in costume jewellery had become apparent, a small number of **national costume jewellery associations** were approached by email with a short list of questions, which included the following:

- *whether cadmium is used in costume jewellery manufactured by member companies;*
- *whether cadmium had ever been an issue with costume jewellery available on the market in each country; and*
- *what the implications of a total ban, migration limit or concentration limit on the costume jewellery industry might be.*

Similar questions were asked by email to a large number of EU companies manufacturing and retailing jewellery, as well as to trade associations, chambers of commerce and individual manufacturers of jewellery in a number of non-EU countries, which had been identified as possible origins of cadmium-containing jewellery imported into the EU. The details of these non-EU organisations were obtained with the kind assistance of the EU delegations in these countries.

Manufacturers and suppliers of cadmium-bearing alloys (solders) were approached with questions similar to those for manufacturers and suppliers of brazing alloys, as described under the brazing section of this note. Some additional questions sent by email focused on the availability of alternatives for cadmium-bearing pink gold solders, such as:

- *the locations of EU companies using such solders;*

- *the size of the market for jewellery articles containing pink gold solders; and*
- *the cost of alternatives to cadmium-bearing pink gold solders.*

In addition, several companies that seemed to be active in the **supply of electroforming materials** to the EU jewellery making industry were contacted. A teleconference was also held with a leading supplier. Key questions asked included the following:

- *whether cadmium is used in electroforming in the EU. If yes,*
    - *which electroforming method(s) use cadmium?*
    - *what concentration of cadmium is used and in what form?*
    - *what is the thickness of the plated material on the final article and what is the concentration of cadmium in it?*
- *whether electroforming is equally popular in both the EU and non-EU countries;*
- *what types of jewellery can be prepared with cadmium electroforming? Is it correct to assume that only costume (rather than precious metal) jewellery is subject to electroforming; and*
- *whether any research has been conducted on the possible migration of cadmium from jewellery articles made with cadmium electroforming.*

Email communication was also undertaken with a range of **companies refining precious metals** in the EU. Questions addressed to these companies included:

- *Can you confirm that your company refines/recycles old jewellery? If yes, please explain whether the presence of cadmium (usually present as a result of gold/silver soldering) has been a problem for your refining process.*
- *Can you explain what the fate of cadmium is during the refining process? Is it completely separated from the precious metals? How is it then handled/disposed of?*
- *Would you agree that round 90% of what EU refineries are processing is old jewellery?*
- *In your experience, is cadmium present in old jewellery that is manufactured in the EU or in non-EU countries (e.g. Asia) or possibly both?*
- *Would a ban on cadmium in jewellery sold in the EU have any adverse or beneficial effect to your operations?*

Other consultees with a significant input to the impact assessment included experts in migration from jewellery, assay offices and RAPEX offices in EU Member States. All participants were approached by email and with occasional phone calls.

Assay Offices in several EU countries were initially approached with the following list of questions:

- *Does your office undertake jewellery testing for cadmium? If yes, please explain:*

- *what types of clients usually request such testing? For instance, do you receive requests from jewellery importers to test articles they import from non-EU countries? If this is the case, how samples are taken?*

- *is it requested for both fine and inexpensive costume (fashion jewellery)?*

- *does it include testing for cadmium concentration only or for cadmium migration too?*

- *what testing methods are used in each case?*

- *what is the cost of testing for cadmium?*

- *Do you hold any information from previous research/testing on the presence of cadmium in jewellery?*

- *Does your experience suggest that cadmium is mainly found in costume jewellery articles imported from non-EU countries?*

Of particular importance have been the inputs of the Assay Offices of the Czech Republic, Latvia and Valencia in Spain with which more in-depth email communication ensued. The Valencia Assay Office in particular was able to provide extensive written input on heavy metals in jewellery which has been presented in detail in the impact assessment report.

Finally, a special mention should be made to an **expert who sits on a relevant Technical Committee of the European Committee for Standardization (CEN)** who was extremely helpful by answering questions pertaining to testing for cadmium, the suitability of different testing methods and the relevant jewellery markets in the EU.

3.1.3. Views of Consultees on the Proposed Policy Options

As for brazing, for reasons of confidentiality, we cannot provide a detailed account of the views of different consultees on the policy options considered and eventually proposed in the impact assessment report. The following should be considered as a general commentary:

- limited input was received from the EU-based jewellery trade associations and individual companies as a result of the apparent limited (intentional) use of cadmium-bearing materials in jewellery making. Concerns with an EU-wide restriction were raised by a small number of companies involved in costume (pewter) jewellery who feared that a strict concentration limit on cadmium might affect their ability to purchase and use pewter containing small levels of the metal;

- also limited information was collected from non-EU trade associations and companies. There were mixed reactions to the prospect of an EU restriction by a small number of organisations, depending on whether they believed that such a restriction would affect negatively or positively their jewellery exports into the EU. There were some organisations suggesting that cadmium is not an issue for jewellery articles manufactured in their countries;

- among the manufacturers and suppliers of alloys and solders contacted, there were some who did not express a direct objection to an EU-wide restriction on cadmium, although they were others who stressed that, in their opinion, the lack of suitable, similarly priced

alternatives functioning at the same temperature ranges would mean that a restriction might have negative impacts on the EU jewellery industry. On the other hand, the limited information received from precious metal refiners suggests that this group of stakeholders could welcome a restriction as the absence of cadmium from scarp jewellery would somewhat simplify their industrial processes;

- a leading supplier of electroforming materials had a positive outlook for a restriction on cadmium given that they could provide alternative systems to their customers and considering the relatively small size of the electroforming market in the EU; and

- finally, experts such assay officer representatives generally did not express an opinion on an EU-wide restriction. Some of them did not have much experience with cadmium (as their offices tend to handle precious metal jewellery articles), while others simply provided information on their experiences with detecting cadmium in samples submitted to them. A small number of consultees, however, expressed concern on the presence of cadmium (and of other heavy metals) in jewellery sold to consumers in the EU.

It should also be noted that the final proposal for policy intervention for cadmium in jewellery is a complex one which was developed towards the end of the preparation of the impact assessment report through information collection and discussions with experts and stakeholders after the main part of consultation with many stakeholder groups had largely been completed.

4. CONSULTATION ON PVC

4.1.1. Overview of Consultees

The following table summarises the categories of consultees contacted in the wider EU PVC industry for the purposes of the impact assessment and the number of responses received.

Table 4: Overview of Consultation on Cadmium in PVC in the EU			
Category of consultees	Number contacted	Number of responses	Locations
PVC extruders, end-product manufacturers and retailers	47	3	CZ, DK, FI, DE, EL, IT, LT, NL, SK, UK
Companies producing recyclate through mechanical recycling	1	1	UK
Companies using recyclate in feedstock recycling	1	1	DE
Virgin PVC manufacturers	1	1	UK
Manufacturers/retailers of extrusion/co-extrusion machinery or manufacturers of parts for extrusion/co-extrusion machinery	16	5	AT, DE, IT, NL
European and national trade associations	6	6	EU, DE, UK
Academic/research experts	2	2	BE, SK
Totals	74	19	

4.1.2. Forms of Consultation

The main form of consultation used was email communication, although specifically for our analysis on cadmium in PVC recyclate numerous teleconferences were held with European associations, companies as well as VITO, to obtain information on:

- *the markets for PVC products in the EU;*
- *the usage of PVC recyclate in the EU, including concentrations, differences between different products and trends; and*

- *the statistics on past usage and the modelling of future usage undertaken by VITO on behalf of the EU PVC industry. Several questions were addressed to both VITO and the relevant EU trade associations with the aim of clarifying specific information and figures presented in the VITO report.*

In the period of preparation of the impact assessment we requested from **ECVM** the following information (by email – additional issues were discussed over several teleconferences):

- *information on the current and foreseeable split between landfilling and incineration of PVC waste in the EU;*
- *information on imports of PVC in the EU and the presence of cadmium in them;*
- *information on exports of PVC building waste from the EU;*
- *numbers and locations of companies involved in the relevant supply chains (PVC waste collection, PVC waste processing, PVC product manufacture) and associated employment figures for each type of building product;*
- *information on the available EU production capacity for each type of building product and the cost of increasing capacity;*
- *information on the return on investment in co-extrusion equipment considering that recyclate is cheaper than virgin PVC;*
- *information on differences between Member States in respect of co-extrusion capacity and recycling activities; and*
- *the industry's willingness to engage in a voluntary* agreement.

In our discussions with companies involved in **mechanical recycling**, issues that we raised included:

- *what are the processes used;*
- *what is the composition of recyclate;*
- *what is the structure of the supply chain and the employment levels in the sector;*
- *what is the current recycling capacity and the price of inputs and outputs;*
- *what are the possibilities to measure cadmium content in recyclate; and*
- *what the impacts would be from different policy options.*

With regard to **chemical recycling**, information requested included:

- *data and information (inputs, processes, outputs) on chemical recycling of PVC waste requested; and*

- *information on past efforts to set up chemical recycling plants in the EU and on future potential of chemical recycling*.

With regard to the **manufacturers of PVC articles** (profiles and non-pressure pipes), information was sought on:

- *recycling processes (inputs, processes, future developments under 'business as usual');*
- *the characteristics of products that contain recyclate (max. recyclate content);*
- *the number and location of companies and/or industrial installations that*
    - *manufacture PVC articles in the EU;*
    - *use recyclate;*
- *the breakdown between small/medium/large enterprises among these companies;*
- *waste collection systems and the relevant supply chains;*
- *the number of installations that can and cannot use co-extrusion at present and any concrete plans to increase co-extrusion capacity in the future?*
- *the cost of converting a mono-line pipe extruder to a co-extrusion line;*
- *the use of foamers and fillers in non-pressure pipes; and*
- *the impacts from the introduction of different limits or revocation of existing limits on the concentration of cadmium in new PVC articles placed on the EU market (the impact of introducing a 100ppm cadmium concentration limit in new profiles that contain recyclate (potentially with a less strict limit in case of strict closed loop recycling) and the impact of revoking the 100ppm limit on new non-pressure pipes that contain recyclate and economic valuation of any impacts).*

Regarding **manufacturers of extruders/co-extruder machinery**, information was requested on:

- *the size of the European market with extrusion and co-extrusion machinery;*
- *the market share of extrusion vs. co-extrusion machinery used in the manufacture of PVC profiles and pipes; and*
- *the cost and performance characteristics of extrusion* vs. co-extrusion equipment.

However, companies that were contacted stated that they did not produce machinery for the production of PVC pipes and profiles. Some limited information on the market with extrusion/co-extrusion machinery and price characteristics was provided.

4.1.3. Views of Consultees on the Proposed Policy Options

Through consultation it was made clear that the EU PVC industry would be very keen to continue using PVC recyclate. It was further argued that the existing legislation, especially with regard to the use of recyclate in non-pressure pipes and round cable ducts, is hindering

the use of recyclate (as a 100 ppm limit currently applies for these products). Therefore, industry was generally in favour of a revocation or relaxation of the existing limit for non-pressure pipes and the maintenance of the status quo for profiles which would allow the uninterrupted use of PVC recyclate.

With particular regard to profiles, a 1000 ppm limit was often perceived as an acceptable solution, especially compared to the prospect of a 100 ppm limit, although some consultees did express concern on whether this limit could easily be met. A suggestion was made that the limit was set higher at, say, 2000 ppm.

With regard to non-pressure pipes and square cable ducts, industry would mostly favour an unconditional relaxation of the existing limit, given the real uncertainties of predicting future waste arisings and cadmium concentrations in recyclate and new PVC articles. Therefore, we would expect that a time-limited derogation for non-pressure pipes and square cable ducts may not be entirely satisfactory for some consultees, if the chosen timeframe of the derogation is considered by them to be too short.

5. CONSULTATION WITH MEMBER STATE AUTHORITIES

The input of authorities in all EU Member States has been sought throughout the development of the impact assessment report. The views of Member States on a range of policy options were collected and presented in the RPA report, more specifically in Tables 4.3 (Section 4.2.2, p31), Table 5.1 (Section 5.2.6, p104), and Table 6.12 (Section 6.2.3, p173).

Annex III: Other EU policies in order to reduce exposure to cadmium

Waste Framework Directive 2008/98/EC, EU policy on sustainable development. The European Union's approach to waste management is based on three principles (1) waste prevention, (2) recycling and reuse, and (3) improving final disposal and monitoring with a preference to safe incineration. Landfill should only be used as a last resort.

EU policy on protection of workers, Framework Directive 89/391/EEC, is based on the approach that workers exposure should be eliminated or where this is not possible the risks should be assessed and appropriate risk management measures introduced with control at source being the preferred control mechanism and PPE used only as a last resort.

Article 16 of the Framework Directive foresees the adoption of individual directives covering specific subjects. In particular, as regards exposure to chemicals EU Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work introduce minimum requirements for worker protection. It is the responsibility of the individual Member States to introduce national implementing legislation that may be more protective than the directives. Protection of workers is covered by the Directive on Personal Protective Equipment (PPE) 89/686/EEC. . An important aspect is that these measures do not cover self employed people.

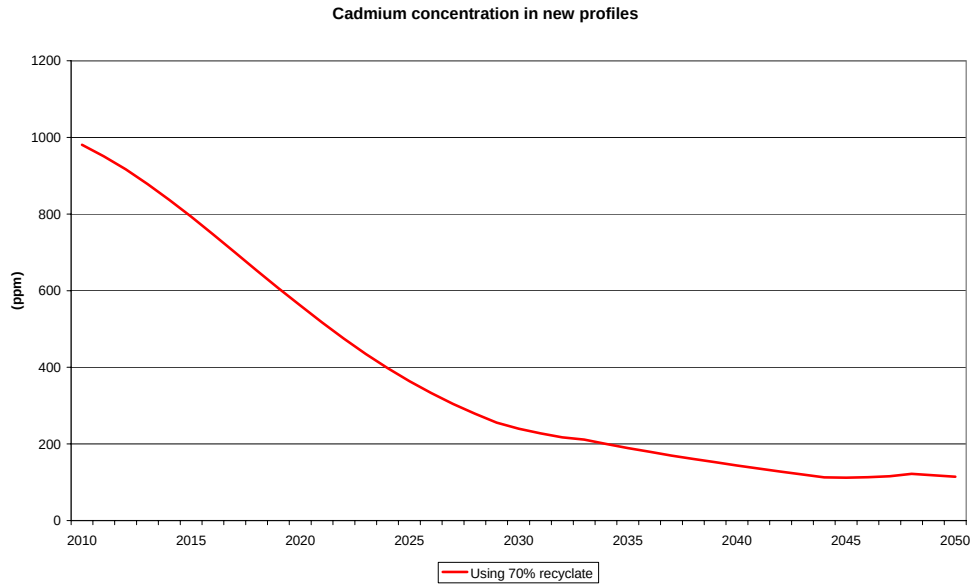
Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC.

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment 2002/95/EC commonly referred to as the Restriction of Hazardous Substances Directive or RoHSE.

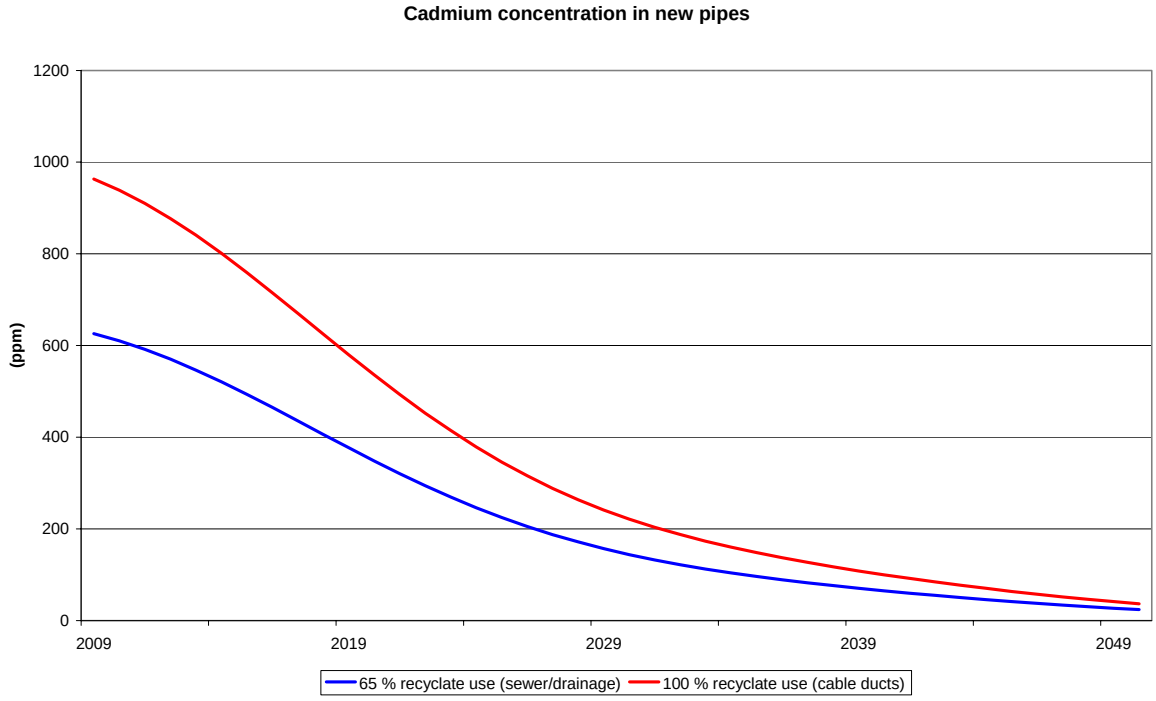
Construction Products Directive 89/106/EEC.

Annex IV: The models for cadmium content of new profiles and non-pressure pipes using PVC recyclate (VITO 2009)

Calculated Concentration of Cadmium in Profiles made from Recycled PVC in the EU using 70% PVC Profile Waste Recyclate



Calculated Concentration of Cadmium in New Non-pressure PVC Sewage/Drainage Pipes and Round Cable Ducts Manufactured in the EU using 65% or 100% Mixed Rigid PVC Waste Recyclate



Annex V: Calculation of health benefits and costs

Brazing Materials – extract from RPA report – Annex 6.4 (RPA, 2009)

A6.4 Calculation and Monetisation of Population Effects from Cadmium Exposure during Brazing

6.4.1 Professional Use

There is insufficient information available with which to assess, on a population basis, the numbers of acute incidents that may arise as a result of short-term high exposures during professional use of brazing alloys containing cadmium. However, estimates of the possible disease burden and associated economic costs have been developed for two long-term health effects (lung cancer and emphysema) since there are sufficient data available to estimate the potential savings that might accrue from the withdrawal of cadmium-bearing brazing alloys.

Lung Cancer

An approach developed by Imperial College London and the Health and Safety Laboratory uses an attributable fraction (AF) model to derive estimates of the number of deaths for particular types of cancer in a given year that can be attributed to exposure to a given agent over a defined period. This approach can also be adapted to allow the estimation of potential changes in disease burden (in terms of deaths for a specified year) that might occur if either the numbers exposed or the period over which exposure occurs is changed.

For Great Britain, the number of deaths from lung cancer attributable to cadmium exposure has previously been estimated (HSE, 2007; HSE, 2007b). A meta-analysis of available epidemiological studies allowed the derivation of a meta-standardised mortality ratio (a meta-SMR[39]) of 1.19 (95% CI 1.09-1.29) for highly exposed worker groups (as defined for the UK by CAREX). A meta-SMR of about 1.0 was found to be appropriate for low and background exposure worker groups. Through application of Levin's equation, this information permitted the derivation of the AF of lung cancer deaths; these were, for men, 0.07% (0.03% - 0.11%), and, for women, 0.04% (0.02% - 0.06%). From these data, it was estimated that, in Great Britain, the attributable deaths from lung cancer in 2004 from occupational cadmium exposure amounted to 13 men and 5 women.

The CAREX dataset on which this estimate is based also provides data on the number of workers exposed to cadmium in the remaining EU-15 countries[40] for the period 1990-1993 (FIOH, 1998), and estimates of the total workforces in these countries for relevant industries (FIOH, 1998b). In order to predict the possible health benefits of a ban on use of cadmium in brazing alloys in terms of future annual savings in deaths from lung cancer, a historic 'baseline' estimate of the attributable lung cancer burden for all workers in the EU-15 was first calculated; these calculations assumed that no additional risk reduction measures had been put in place (i.e. calculations for the EU-15 were based on identical exposure assumptions as used in the Imperial College/Health and Safety Laboratories study on workers in Great Britain). Furthermore, it was assumed that changes in the size of workforce, turnover

[39] The ratio of observed to expected deaths from a specific condition based on data pooled from a number of studies.

[40] Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain and Sweden.

rate and exposure patterns in the various industries and the within-industry sex distribution of the EU-15 cohort were essentially identical to those for the Great British worker cohort. This allows a baseline estimate of attributable lung cancer deaths to be made using the CAREX European cohort.

Based on these assumptions, the number of attributable deaths due to lung cancer as a result of cadmium exposure for the EU-15 cohort in 2004 was estimated to be 127 (95% CI: 61 - 193; see Table A6.10). It should be noted that this estimate is of value only as a baseline against which to judge the possible size of the reduction in lung cancer burden that might be achievable as a result of the withdrawing the use of cadmium-bearing brazing alloys.

Table A6.10: Attributable Deaths from Lung cancer in Europe due to Cadmium Exposure – Assuming No Change in Exposure Conditions

	Males	**Females**	**Total**
Attributable deaths	109	18	**127**
95% Confidence Interval	52	9	**61**
	166	27	**193**

In order to estimate the range of possible reductions in lung cancer deaths that might occur following withdrawal from use of brazing alloys containing cadmium, the above process was repeated with values being recalculated for two possible scenarios.

Maximum Potential Reduction Scenario

Predictions of the maximum potential reduction in future cases are based on the assumption that there has been no change in workers' exposure profiles except for the EU-wide ban on use of cadmium in electrical equipment that was assumed to have removed '*Manufacture of electrical machinery, apparatus, appliances*' workers from risk of cadmium exposure. It is also assumed that withdrawal of cadmium containing brazing material alone would be sufficient to reduce worker exposure in the '*Manufacture of fabricated metal products'* and the '*Manufacture of machinery, except electrical'* sectors so they become a low exposure group (i.e. no longer at elevated risk of cadmium-induced lung cancer).

More Realistic Reduction Scenario

While the maximum potential reduction scenario is of interest, it is recognised that, in addition to the EU ban on cadmium in electrical equipment, other measures are already in place that will have already have significantly reduced worker exposure to cadmium. Such further measures include, for example, general improvements in occupational hygiene standards by industry, together with specific measures prompted for example by the classification of cadmium as a carcinogen.

Therefore, to generate a somewhat more realistic scenario of the potential benefits that might arise from the proposed measure, it must be recognised that the potential impact that could arise from the proposed restriction would only impact on that part of the entire workforce which for one reason or another (e.g. due to poor implementation of existing legislation or

employees lack of access to, or unwillingness to use, PPE) may not yet be subject to adequate protection despite the various existing measures.

To adjust for the independent protective effect of the various measures already introduced, for simplicity, it is assumed that 70% of European workers would already be adequately protected from cadmium fume exposure. Withdrawal of cadmium-containing brazing materials would therefore only impact on the risk of lung cancer development for a maximum of only 30% of the relevant workforce sub-population.

Predicted Reductions in Excess Deaths

Recalculating the attributable lung cancer deaths for each scenario gives an attributable lung cancer death estimate of 98 (CI: 47 - 148) for the **'maximum potential reduction'** scenario; for the '**more realistic'** scenario, the estimate of attributable lung cancer deaths is 121 (CI: 58 – 184; see Table A6.11 for further details).

Table A6.11: Attributable Deaths from Lung Cancer in Europe due to Cadmium Exposure – for 'More Realistic' and 'Maximum Potential' Scenarios (2004)

Scenario		**Males**	**Females**	**Total**
'More realistic'	Attributable Deaths	104	17	**121**
	95% Confidence Interval	50 – 159	8 – 184	**58 -184**
'Maximum potential'	Attributable Deaths	84	14	**98**
	95%Confidence Interval	40 – 127	7 - 21	**47 - 148**

Comparing the two scenarios against the baseline indicates the potential reduction in annual lung cancer deaths that might be achieved by the proposed ban on cadmium-containing brazing alloys:

- the more realistic scenario suggests that, for the EU-15, a reduction of **6 (CI: 3 - 9) lung cancer deaths per annum** may be possible;
- the (highly unlikely) maximum reduction that might accrue is **29 (CI: 14 - 45) deaths from lung cancer per annum**.

It should be noted however that, because of the long latency of this disease (taken as between 10 and 50 years in the Imperial College study), it will be many years before any such improvements become evident.

Occupationally-related Emphysema

HSE (2008) presents information on the annual incidences of physician-diagnosed cases of occupationally-related emphysema for a range of agents. For cadmium, the qualifying criteria for recognition of a claim for industrial compensation is that the individual must have inhaled cadmium fumes for a total aggregated period of at least 20 years (UK Government, 2007). HSE report that, over a 10 year period, sufficient evidence to qualify for industrial compensation was attained for only five individuals suffering from emphysema due to

cadmium exposure (i.e. average incidence of 0.5 cases per year for the British workforce). A report based on data from Eurostat (2009) presents information on the size of, and occupational diseases suffered by, the working population in Europe and gives the size of the UK workforce as 27,863,000 in 2002.

Two possible scenarios are considered to estimate the possible reduction in occupationally-induced emphysema that might arise in Europe from withdrawal of cadmium containing brazing materials.

Maximum Potential Reduction Scenario

In this scenario, it is assumed that there has been no change in workers' exposure profiles that would influence the incidence of occupational emphysema, and that withdrawal of cadmium-bearing brazing alloys alone is sufficient to reduce exposure levels such that there is no longer an elevated risk.

Assuming that all the observed cases of cadmium-induced emphysema in the UK arose from exposure to cadmium from welding/brazing activities and extrapolating the UK incidence to the contemporaneously estimated total workforce for the EU-15 (160,806,000) would suggest that the total annual incidence of cadmium-induced emphysema (of sufficient severity to qualify for industrial compensation under UK law) may be 2.9 cases.

Applying the same incidence to more recent estimates of the size of the European labour force for the fourth quarter of 2008 (176,973,800 workers for EU-15 and 221,752,800 for EU-27 (Eurostat, 2009b)) suggests possible **total annual incidences of cadmium-induced emphysema (of sufficient severity to qualify for industrial compensation under UK law) of approximately 3.2 cases for the EU-15 and 5.0 cases for the EU-27**.

It is generally assumed that the incidence of workers suffering work-related health impairments as a result of a work-related exposure is at least 10-times that recorded for physician-diagnosed occupational cases for any given agent (Leigh *et al*, 1999; Driscoll *et al*, 2005; Diepgen & Kanerva, 2006). Thus, it may be postulated that, again based on estimates of the size of the Eurostat workforce in 2008, as a worse-case estimate **the number of cadmium-related cases of emphysema per annum in the EU-15 may be of the order of 30 and there may be up to 50 cases in the EU-27.**

More Realistic Reduction Scenario

In generating a more realistic reduction scenario, it has been assumed that a wide range of existing risk management measures will have already reduced many workers' exposure to cadmium.

To adjust for the independent protective effect of the various measures already introduced, for simplicity, it is assumed that 70% of European workers would already be adequately protected from cadmium fume exposure. Withdrawal of cadmium-containing brazing materials would therefore only impact on the risk of emphysema for a maximum of 30% of the workforce.

Using the Eurostat (2009b) estimate of labour force size, the number of potential cadmium-induced emphysema cases (for which there would be sufficient evidence to qualify for

industrial compensation under UK law) is approximately 0.96 cases in the EU-15 and 1.5 cases for the EU-27 per annum.

As for the maximum reduction scenario, the real figure may be 10 times these estimates; i.e. 9 cases for the EU-15 and 15 cases for the EU-27.

It should be noted that emphysema has a long latency (of the order of decades) so it may be many years before any improvements become evident.

A6.4.2 Hobby Use

Extent of Exposure due to Hobby Use

Estimates of the cadmium burdens that might potentially arise during a series of DIY, semi-professional and professional scenarios, are detailed in earlier in this Annex and are also summarised in Table A6.12 where they are compared against the recently revised European tolerable weekly intake (TWI) value for cadmium of 2.5 µg/kg bw/wk (EFSA, 2009). It is apparent that for only two of the scenarios considered does the estimated additional burden from use of cadmium-containing brazing alloys represent appreciable (>1%) contributions to the TWI.

These scenarios are '*DIY - high maintenance - no ventilation*' (which may contribute approximately 3% of TWI) and '*DIY - boiler making - heavy user, natural ventilation*' (approx. 4% of TWI).

The model used to estimate these additional burdens from inhalation of cadmium during welding and brazing includes an adjustment for inhalation-specific absorption characteristics (i.e. it is assumed that only approximately a quarter of inhaled cadmium is expected to be absorbed). However, use of this adjustment is specifically excluded from the EFSA model when considering non-dietary sources of exposure. Therefore, for illustrative purposes, estimates are also presented for the scenarios excluding the route-specific adjustment to intake.

Without adjustment for absorption, the two identified scenarios ('*DIY - high maintenance - no ventilation*' and '*DIY - boiler making - heavy user, natural ventilation*' (approx. 4% of TWI) can be seen to represent an appreciable additional source of cadmium (11% and 45% of TWI respectively).

Table A6.12: Estimated Additional Cadmium Burden arising from Various Exposure Scenarios

Scenario	**Weekly additional Cd burden (µg/kg bw/wk)**	**Weekly additional Cd burden (as % of TWI[1])**	**Weekly additional Cd burden - no adjustment for absorption[2] (µg/kg bw/wk)**	**Weekly additional Cd burden – no adjustment for absorption[2] (as % of TWI[1])**
DIY - average user - no ventilation	**0.02**	**1%**	0.09	**4%**
DIY - average user - natural ventilation	0.01	0%	0.03	1%
DIY - average user - wall fume extractor	0.00	0%	0.00	0%

Table A6.12: Estimated Additional Cadmium Burden arising from Various Exposure Scenarios				
Scenario	**Weekly additional Cd burden (µg/kg bw/wk)**	**Weekly additional Cd burden (as % of TWI[1])**	**Weekly additional Cd burden - no adjustment for absorption[2] (µg/kg bw/wk)**	**Weekly additional Cd burden – no adjustment for absorption[2] (as % of TWI[1])**
DIY - high maintenance - no ventilation	**0.07**	**3%**	0.28	**11%**
DIY - high maintenance - natural ventilation	0.02	1%	0.09	**4%**
DIY - high maintenance - wall fume extractor	0.00	0%	0.00	0%
DIY - high maintenance - personal fume extractor	0.00	0%	0.00	0%
DIY - boiler maker -natural ventilation	**0.07**	**3%**	0.19	**7%**
DIY - boiler making - wall fume extractor	0.00	0%	0.01	0%
DIY - boiler making personal fume extractor	0.00	0%	0.00	0%
DIY - boiler making - heavy user, natural ventilation	**0.11**	**4%**	1.11	**45%**
DIY - boiler making - heavy user - wall fume extractor	0.00	0%	0.05	2%
DIY - boiler making - heavy user - personal fume extractor	0.00	0%	0.00	0%
Pro/DIY - heavy user - wall fume extractor	0.01	0%	0.05	2%
Pro/DIY - heavy user - personal fume extractor	0.00	0%	0.00	0%

Notes:

1 Tolerable weekly intake for Europe of 2.5 µg/kg bodyweight/week (EFSA, 2009).

2 Assuming no adjustment is made for route-specific absorption for non-dietary sources, as adopted by EFSA (2009)

Possible Health Consequences of Elevated Cadmium Exposure Due to Hobby Use

The dietary exposure to cadmium in the general European adult population is believed to be relatively high (1.9 to 3.0 µg/kg bodyweight/week) and some groups with particular diets are thought to have higher intakes (2.5 to 3.9 µg/kg bodyweight/week). The average European dietary cadmium intake is thought to be close to or to exceed the TWI of 2.5 µg/kg

bodyweight/week (EFSA, 2009). For current purposes, it may be assumed that any additional cadmium exposure from non-dietary sources such as occupation, smoking or the hobby activities will result in overall cadmium intake in excess of the TWI; this could have potential adverse health consequences for exposed individuals.

EFSA (2009) has established urinary cadmium level as an important indicator of long-term exposure levels and epidemiological studies have shown that this biomarker is associated with a number of adverse chronic health outcomes. In particular, EFSA notes that at urinary concentration of 1 µg Cd/g creatinine only minor changes in renal markers occur and this was set as a reference level. EFSA also estimated that 95% of the population at age 50 would have urinary cadmium levels below the reference point if dietary intakes did not exceed TWI. A slightly higher urinary level of 2 µg/g creatinine was established as an appropriate LOAEL (based on renal and bone effects) in the Cd RAR (EC, 2007) thus emphasising that there may be adverse consequences, on a population basis, in groups with elevated urinary cadmium levels.

Applying the approach of Amzal *et al* (2009) - as adopted by EFSA (2009) - permits an approximation to be made of the proportion of an exposed population that may exceed a particular urinary cadmium level for a given cadmium intake. For the two scenarios identified above where some cause for concern was apparent (see Table A6.12), the urinary cadmium levels and associated health consequences were assessed. Estimates of the percentage of the exposed population with urinary cadmium levels in excess of 1, 2 or 3 were derived (see Table A6.13).

While the proportion predicted to potentially exceed the reference level (1 µg/g creatinine) or LOAEL (2 µg/g creatinine) are very low if the extent of absorption via inhalation is adjusted for, if no adjustment for inhalation absorption is included, then for the '*DIY - boiler making - heavy user, natural ventilation*' scenario, **15%** of the group would exceed the 1 µg/g creatinine level and approximately **2%** would exceed 2 µg/g creatinine.

Table A6.13: Estimated Distribution of Urinary Cadmium in Exposed Populations under Specified Scenarios									
Scenario	**Weekly additional Cd [1] (µg/kg bw/wk)**	**Total weekly Cd intake[2] (µg/kg bw/wk)**	**Total weekly additional Cd burden - no adjustment for absorption[3] (µg/kg bw/wk)**	**Percentage of population (approx.) with urinary Cd level above**					
				Adjusted for route-specific absorption			**Not adjusted for route-specific absorption**		
				1 µg/g creatinine	**2 µg/g creatinine**	**3 µg/g creatinine**	**1 µg/g creatinine**	**2 µg/g creatinine**	**3 µg/g creatinine**
DIY - high maintenance - no ventilation	0.07	2.57	2.78	2	0	0	2	0	0
DIY - boiler making - heavy user, natural ventilation	0.11	2.61	3.61	3	0	0	15	2	0

Notes:

1 Estimated additional Cd burden for scenario (no route-specific adjustment)

2 Assuming cadmium exposure from stated scenario and a dietary intake of approximately 2.5 µg/kg bodyweight/week but no other sources (e.g. smoking)

3 Assuming cadmium exposure from stated scenario with no route-specific adjustment for absorption and a dietary intake of approximately 2.5 µg/kg bodyweight/week but no other sources (e.g. smoking)

Although these estimates are inexact and not entirely robust, they inform on the possible proportions of these population sub-groups at risk of adverse health effects. For example, in a study by Nawrot *et al* (2008) on an environmentally-exposed adult cohort living in Belgium, over a follow-up period of 20 years (median), the excess risk associated with a doubling of baseline urinary cadmium level was found to be approximately 20% and 43%, for total and non-cardiovascular deaths respectively (see Table A6.14). These values are not dissimilar to an estimate for 'all causes of death' of 1.28 (1.15 - 1.43) for a doubling of urinary cadmium levels in a US-based study (Menke *et al*, 2009).

Table A6.14: Risk of Mortality Associated with Exposure to Cadmium

Death	**Standardised rate (per 1000 person-years)**		**Hazard ratio*** **(95% CI; p-value)**
	Low exposure	**High exposure**	
Total (any cause)	11.0	13.8	1.22 (1.06 – 1.40; 0.006)
Non-cardiovascular causes	5.2	6.5	1.43 (1.17 - 1.76; 0.0007)

Source: Nawrot et al (2008)

*Note: * hazard ratio associated with doubling of urinary cadmium level*

As noted elsewhere in this report, it has been estimated that there may be as many as 112,500 DIY boiler makers in Europe that may use cadmium-containing brazing materials. If it is assumed that 5% (5,625) of DIY boiler makers may fall into the scenario '*DIY - boiler making - heavy user, natural ventilation*' and that this level of hobby activity is maintained for a considerable proportion of their adult life, then applying the approach of Amzal *et al* (2009) would indicate that up to **2% (113)** of this sub-group may have urinary cadmium levels twice the EFSA reference level.

Based on the excess risk estimates for a 20-year follow-up (Nawrot *et al*, 2008), this sub-group might therefore be at similar elevated risk (of any cause or non-cardiovascular death) when compared with a population exposed at only the TWI. A crude death rate for adults of 1,032 deaths per 100,000 is available for the European Union (Eurostat, 2009):

- applying the '**all causes**' hazard ratio for a doubling of urinary level (1.22) to this crude death rate would suggest that the **additional burden on the '*DIY - boiler making - heavy user, natural ventilation*' group** may be of the order of **1.4 deaths** (lifetime risk). If the risk estimate for '**non-cardiovascular causes**' (1.43) is applied, the **additional burden estimate is** slightly higher at **1.7** (lifetime risk); and

- alternatively, age-standardised death rates (per 100,000) are available for the year 2006 for EU-15 (576.5) and for EU-27 (640.9; Eurostat 2009c). Using these rates, would give an additional burden of 'all cause' deaths of **0.79** for EU-15 and **0.88** for EU-27; for non-cardiovascular deaths, the figure would be **0.93** for the EU-15 and **1.04** for the EU-27.

A6.4.3 Economic Value of the Reduction in Health Burden

Introduction

Table A6.15 provides a summary of the potential health benefits to professional and hobby users of restrictions on the use of cadmium in brazing alloys. In the remainder of this section, we use benefit transfer techniques to convert the predicted reduction in health impacts to a monetary measure of benefits. The aim of this exercise is to translate the reductions in impact to a welfare economics-based value that can be compared more directly with the costs of any restrictions. This is done by applying economic valuations to the number of cases predicted as being avoided in the future, as reported in Table A6.15.

Table A6.15: Predicted Reduction in Health Burden with Restrictions on Cadmium in Brazing

		Excess mortalities/cases for different scenarios		**Cases per annum over 20 years**	
		Low	**High**	**Low**	**High**
Professional use					
Lung cancer		6	29	6	29
Emphysema		9	15	9	15
Hobby Use					
5% DIY boiler makers - Exceedance TWI	Crude death rate	1.4	1.7	0.07	0.09
	Age standardised	0.88	1.04	0.04	0.05
Notes: Based on 'More Realistic Scenario' for lung cancer and emphysema					

From a welfare economics perspective, the social costs associated with mortality or morbidity impacts can be divided into three categories: health service costs; productivity costs; and the value of the lost health-related quality of life to the individual.

The estimation of health service costs is relatively straightforward and is usually based on estimates available from the published literature or from health care authorities. Productivity costs refer to the value of production lost as a result of the ill health, disability or death of an individual. In a SEA, costs (usually valued at the wage rate) are incurred wherever there is lost productivity, either as a result of a change in an individual's productivity rate in the same job or due to an individual only being able to undertake less productive work. When an individual is off work due to an occupational illness or is unable to continue in a higher paid job, they may experience a loss of income.

The final cost category is defined as the monetary value of the loss of health-related quality of life per se, with this reflecting only the non-financial aspects of having an illness. Where willingness to pay valuations exist for the disease of concern or to avoid the risk of death, then these can be used to calculate the economic value of changes in the number of disease cases. Where such valuations do not exist, it may be possible to derive an appropriate valuation by transferring a value for another, similar health impact or by linking changes in quality of life (e.g. using QALYs) to monetary values.

Valuation of a Mortality Avoided

The SEA Guidance for preparing a Restrictions Dossier (ECHA, 2008) provides unit costs for mortality and morbidity linked to exposure to pollution. The figures quoted in the Guidance for mortality due to chemicals exposure are given in Table A6.16 below, in 2008 price levels. Note that these figures include some allowance for health care costs, productivity costs and the lost health-related quality of life (although they may not reflect the full health care costs, for example, associated with treatment of cancer).

Table A6.16: Reference Values for Chemicals and Mortality (2008 prices, rounded)

Values	**Central value**	**Sensitivity value**
Value of a statistical life	€1,207,700	€2,592,100
Value of a life year lost	€64,100	€143,700

Source: ECHA (2008)

Notes: Updated from 2003 prices using OECD price indices statistics

These figures relate to environmental pollution more generally and, thus, may reflect a largely elderly population where the reduction in life expectancy is likely to be short. Assuming this is the case, it has been argued by a number of economists that the figures should be adjusted to reflect the fact that cancers (including occupational cancers) may affect a population with a more diverse age range. The figures will also fail to account for the fact that people may be willing to pay more to reduce their risk of dying from cancer than to reduce their risk of a death from other illnesses, since the death from cancer may be preceded by a long period of serious illness.

DG Environment (ENVECO, 2001) has argued in the past that a cancer premium of 50% (i.e. multiplying the above estimate by 1.5) should be added to more general environmental pollution Willingness to Pay (WTP) values to capture this period of ill health prior to death. Similarly, research carried out for the US EPA also suggests that such adjustments should be made, but no multiplier is quoted (Alpha-Gamma Technologies, 2006). The UK Health & Safety Executive adopts a multiplier of 2 to account for a cancer premium (although guidance issued by Her Majesty's Treasury on the assessment of health benefits notes that there is no justification for this multiplier).

Applying a multiplier of 1.5 to the VOSL figures given in Table A6.16, would suggest per mortality avoided figures of €1.8 and €3.9 million respectively for the central and sensitivity values. For the purposes of this assessment, we have adopted the figure of €1.2 million for the base case and to reflect a lower bound value of a statistical life (VOSL) which incorporates an individual's willingness to pay to avoid the risk of a death from cancer; and upper bound VOSL of €1.8 million is used for sensitivity purposes.

Note that these estimates relate only to cancer deaths. No robust valuation estimates are available for an individual's WTP to avoid non-fatal cancers have been identified.

Valuation of Occupational Emphysema

Halpin (2006) provides a summary of four burden of illness studies for chronic obstructive pulmonary disease (COPD, of which emphysema is one particular form), which provide information on the direct and indirect costs associated in the UK. Three used a top-down approach while the fourth adopted a bottom-up approach. Once the year in which they were undertaken and differences in their design are taken into account, the studies result in similar estimates of the economic burden of COPD - between £781 and £1,154 per patient per year. These figures include the direct costs of COPD care, including the costs of drugs, physician's time and hospitalisation; they also include the indirect costs associated with lost productivity.

To these costs should be added an indication of an individual's willingness to pay to avoid the decrease in their health related quality of life. However, within the time available we were unable to find a reliable willingness to pay value that could be transferred to the valuation of the increased incidence of emphysema. Some values are available for respiratory effects, but they require data on the number of episodes per annum and it is not clear that they would be a reliable valuation. Use of data on QALYs lost due to emphysema for combination with a monetary value per QALY was also considered, but we were unable to identify a robust QALY value within the time and resources available.

Assumed Monetary Valuations and Predicted Benefits of Restrictions

Based on the above discussion, we have assumed that the economic (monetary) value for each avoided disease case is:

- Lung cancer: €1.2 million lower bound; €1.8 million upper bound
- Hobbyist lifetime risk of death: €1.2 million lower bound; €1.8 million upper bound.
- Emphysema: €1,100 lower bound; €1,600 upper bound.

The figures for lung cancer and the hobbyist lifetime risk of death are per case avoided, while the figures for emphysema are per case per annum. Thus, in estimating the monetary value of the reduction in future health impacts, these figures have to be combined with the estimates of the cases avoided per annum column in Table A6.15 above.

In line with the lifetime risk estimates, the number of cases avoided over a 20-year period is assumed to be most representative of the benefits from a restriction on the use of cadmium in brazing alloys. For aggregation purposes, the monetary value of the benefits per annum over this 20 year period have been discounted at 4% (European Commission rate) and present value estimates produced. These are reported in Table A6.17 for professional users and Table A6.18 for hobby users.

Table A6.17: Present Value Estimates of Avoided Health Impacts – Professional Users				
	Lung cancer		Emphysema	
	Lower	Upper	Lower	Upper
Number of cases per annum	6	9	9	15
€ per case	1,200,000	1,800,000	1,100	1,600
PV - €million	97.85	472.94	0.13	0.22
Notes: Lower and upper bound estimates for the 'More Realistic Scenario'; lower and upper bound economic valuation assumptions also applied. Values for emphysema exclude consideration of willingness to pay for health related quality of life. Discounted at 4% over 20 years.				

Table A6.18: Present Value Estimates of Avoided Health Impacts – DIY Boiler Making, Heavy User				
	Crude death rate		Age-standardised death rate	
	lower	upper	lower	upper
Number of cases per annum	0.07	0.09	0.04	0.
€ per case	1,200,000	1,800,000	1,200,000	1,800,000
PV - €million	1.1	2.2	0.7	1.2
Notes: Discounted at 4% over 20 years.				

As can be seen from Tables A6.17 and A6.18, the present value estimate for the avoided health impacts to professional users are significantly higher than for hobby users. The total present value benefit estimates are around €98 million for professional users and the lower bound set of assumptions, rising to €473 million for the upper bound set of assumptions. The assumptions concerning the number of future cases of lung cancer avoided comprises over 99% of these benefits. The estimated value of the benefits of reduced emphysema cases is low in comparison, although it must be remembered that these do not include any valuation of benefits related to improvements in health-related quality of life.

In contrast, the estimated benefits associated with hobby use are significantly lower. For the scenario based on 2% of the '*DIY - boiler making - heavy user, natural ventilation*' population being at risk, the present value benefits range between €0.7 and €1.2 million. For the crude death rate based estimates, the present value estimates rise to between €1.1 and €2.2 million.

Annex VI: The SME Test

(1) Consultation with SMEs representatives	Section 1.1 of the IA report
(2) Preliminary assessment of businesses likely to be affected	Section 2 of the IA report, more specifically section 2.1.1 for brazing alloys, section 2.1.2 for jewellery and section 2.1.3 for PVC
(3) Measurement of the impact on SMEs	Section 5 and 6 of the Impact Assessment report, sections 5.1 and 6.1 for brazing alloys, section 5.2 and 6.2 for jewellery and section 5.3 and 6.3 for PVC
(4) Assess alternative options and mitigating measures	Section 5 and 6 of the Impact Assessment report, sections 5.1 and 6.1 for brazing alloys, section 5.2 and 6.2 for jewellery and section 5.3 and 6.3 for PVC