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SUMMARY OF THE 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)

Disclaimer:

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

1. Problem definition

Cadmium is a category 1B carcinogen and category 2 mutagen and a reproductive toxicant according to the CLP Regulation (EC) No 1272/2008 Annex VI. Restrictions on cadmium are incorporated in entry 23 to Annex XVII to REACH (no restriction for cadmium-bearing brazing alloys and jewellery, restriction on the use of cadmium as stabiliser for PVC for a limited number of applications). A risk assessment pursuant to the Regulation No 793/93, performed by Belgium, and adopted in 2008¹ concludes that there is a need for specific measures to limit the risks in brazing materials and jewellery.

Exposure to cadmium from brazing materials and jewellery for workers and consumers comes from inhalation (fumes) and skin contact. Environmental exposure comes from release of cadmium through fumes, waste and accidental release. For brazing applications alternatives are available except for specific application in the aviation 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.

For PVC the problem is that it is currently not possible to recycle PVC containing cadmium in certain rigid building products. 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 137² 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.

2. Analysis of subsidiarity

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

3. Objectives of EU initiative

The 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. More specifically to:

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

¹ European Union Risk Assessment Report cadmium metal and cadmium oxide Part I environment (EUR 22919 ENV, Part II Human Health (EUR 22766 EN)

² Art. 137 of REACH deals with the transitional measures regarding restrictions

- 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.

4. Policy options

4.1 Cadmium in brazing alloys

Option B1: Baseline scenario, continuing business as usual

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, meaning that DIY users should no longer be exposed to cadmium release from brazing activities. As it is not feasible to segregate the market of consumer brazing materials from professional use only option B2b will be considered further.

(b) for consumer and professional use: Under this option, a restriction on the use of cadmium would be introduced, 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.

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

(a) for consumer use only: This option, prescribing the use of alloys, gases, use of fume extractors or working outside, 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.

(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 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, this option 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, Option B3b will not be considered further.

4.2 Cadmium in jewellery

Option J1: Baseline scenario continuing business as usual

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.

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 defensible from a human health perspective to set a safe level for cadmium in jewellery and the option is therefore not considered further.

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 and therefore the option is not considered further.

4.3 Cadmium in PVC

Option P1: Business as usual

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 2010³) 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 articles⁴ only if manufactured with PVC recyclate without an upper concentration limit for cadmium and without 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.

³ www.vinyl2010.org

⁴ 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.

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 cadmium in PVC will drop below 100 ppm by 2050. Therefore this option is 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 articles⁵ if manufactured with PVC recyclate with higher concentration limits for different article types

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 ppm⁶, 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 articles⁷ if manufactured with PVC recyclate with higher concentration limits for different article types

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.

5. Assessment of impacts

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. Specific sectors such as aviation and defence technology can continue to use cadmium in specific applications for which currently no alternatives exist. Adverse impacts on the environment will continue because of the release of cadmium during manufacture, disposal and through ventilation systems.

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

⁵ See footnote 4

⁶ The suggested concentration limit of 1,000 ppm is based on a study of VITO, 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 . The concentration of cadmium in PVC containing recycled material is likely to decline below 100 ppm in 2050.

<http://www.vinyl2010.org/images/stories/final%20report%20vito%20study%20on%20cadmium%20in%20pvc%20recyclate.pdf> (VITO, 2009)

⁷ See footnote 4

The total monetised benefit (99.3 - 475 million Euro over 20 years) from a reduction of risk of deaths or disease from exposure to cadmium outweighs the estimated cost (57.8-352 million Euro over 20 years) coming from alternative alloys and gases and additional heating time. The hobby users will have to change habits but enjoyment will only be impacted marginally. Many 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. The Member States most affected will be the UK, Germany, France, The Netherlands and Belgium (RPA, 2009⁸). 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.

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

The overall investment for DIY users 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. For consumers opting to switch to cadmium-free alloys the overall cost is estimated at 3.6-73 million Euro (over 20 yrs). 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) 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.

5.2 Jewellery

Option J1: Business as usual (Baseline Scenario)

In this scenario the use of cadmium for jewellery manufacture would continue and there will be continued exposure of children and adults to cadmium through skin exposure and possibly licking. Most affected are young persons as they are the main consumers of costume jewellery.

Option J2: Complete restriction on cadmium in jewellery articles

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 from reduction of unsafe practice in extracting cadmium from waste and to use that in jewellery making.

The costs for the EU jewellery industry are estimated at 9.8 – 20 million Euro over 20 years. For customers of precious jewellery there may be a small price increase but it will protect

⁸ RPA (2009) 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

them from the malpractice of diluting precious metals. There will be a significant impact on non-EU manufacturers of jewellery due to increased costs of materials and quality control.

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 disposal will increase. Lower levels of recycling mean increased landfilling/incineration which has a negative impact on the environment (through the release of CO₂) and the recycling industry.

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

This option 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 the financial impact for the PVC profile industry is estimated to 1,197-1,227 million Euro extra costs (2010-2050, VITO 2009⁹). 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 CO₂ emissions of 7.2 million tonnes (2010-2050, VITO 2009).

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

The total profit from allowing cadmium to be present in recycled non-pressure pipes, for recyclers and converters, is between 2,312 – 2,783 million Euro, creating 7,095 additional person years in employment (for 2010-2050, VITO 2009). Recycling would save costs of landfilling/incineration estimated to 3.14 million tonnes, representing savings up to 314 million Euro (2010-2050, VITO, 2009). The reduction of landfill and incineration would have a positive impact on health and the environment, the estimated reduction of CO₂ release is 6 million tonnes (2010–2050, VITO 2009).

⁹ VITO (2009): Study on the Cadmium Content of Recycled PVC Waste, Interim Report, 31 March 2009 (provided by the European Council of Vinyl Manufacturers), report by Liesbet Goovaerts, Ive Vanderreydt, Veronique Van Hoof, Karl Vrancken, commissioned by Vinyl 2010.

The use of cadmium in PVC in the EU is expected to be phased-out by 2050 (VITO 2009). The time limit ensures the achievement of the complete ban of cadmium in the future, it acknowledges the efforts of the European PVC industry to reduce the cadmium content and also restricts imports of not recycled cadmium containing PVC into the EU. 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 (VITO 2009). 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 (VITO, 2009) 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.

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 preferred option is 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. This option is therefore proposed in Annex XVII of the REACH Regulation because it meets the objectives, has the highest health benefits, and is coherent with the existing legislative framework

6.2 Jewellery Comparison of Effectiveness and Efficiency of Selected Policy Options

Policy Option	Effectiveness	Efficiency
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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

The preferred option for immediate action would be the adoption of a total restriction on cadmium in jeweleries to be included in Annex XVII of REACH. It meets the objectives, has a positive impact on health, and is coherent with the existing legislative framework.

6.3 PVC Comparison of Effectiveness and Efficiency of 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 recylate 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 recylate	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 is to extend the existing limit of 100 ppm cadmium to all 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, 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.* This option is fulfilling the objectives, has a positive environmental impact and works towards the phasing out of cadmium

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 and one-off costs of alloy manufacturers Benefits to short term exposure could not be included due to the absence of 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 most vulnerable, and in the case of costume jewellery the most important, consumer group Figures do not include costs for importing SMEs Figures do not include costs and benefits for third country companies
PVC – complete restriction on cadmium	1,200 M€(loss in turn-over in recycling, employment and		Estimates over 40 years from 2010-2050

	global warming) 9,200 person years 7.2 M Tonnes CO ₂		
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

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. 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).

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.

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.