

Brussels, 20 April 2018

Position paper on the proposed Occupational Exposure Level for Beryllium

On 5 April 2018, the European Commission published its proposal for binding occupational exposure limit values (OEL) for 5 substances including Beryllium and inorganic beryllium compounds as well as an accompanying executive summary and staff working review reportedly of the Socio-Economic Impact Assessment (SEIA).

The EC's proposal for Beryllium should be rejected as it is flawed for the following reasons:

- **Unreliable data:** As recognized by the EC, the SEIA was conducted on the basis of scarce and/or unreliable data;
- **Overestimation of workers and companies:** An estimated 54000 workers in 5800 companies were likely to be exposed to Beryllium in the workplace. This number is vastly overestimated based on the experience and knowledge of the beryllium industry;
- **Overestimation of past and future CBD cases:** Based on questionable information and calculations, an estimated 3807 CBD cases have occurred in the EC during the past 40 years. This number is vastly overestimated compared to the data collected from Member States Authorities by the beryllium industry which found that there have been approximately 20 cases of CBD in the last 10 years. Similarly, the number of future cases of CBD likely to occur in the absence of any further action was vastly overestimated as well.
- **Closures of SMEs:** Contrary to statements made by the EC, the costs associated with compliance to the proposed final binding OEL for beryllium, which is one-tenth of the current median value in the EU, will cause the closure of SME companies and the loss of jobs in the EU;
- **Inconsistency with other regions:** The proposed OEL is not aligned with the OELs applied by other major industrial countries, such as the U.S. and Japan, and will affect the EU industry's competitiveness.
- **Beryllium is a Critical Raw Material (CRM) to the EU:** Beryllium and its alloys are essential and non-substitutable in a wide range of strategic sectors, such as aerospace, energy, automotive, medical, electronics, and defense. The use of beryllium owing to its superior properties is driving growth. An overly restrictive OEL would be contrary to this CRM status, granted by the EC for economic importance and supply risk reasons.
- **Industry Initiatives to Promote Safe Handling of Beryllium;** The beryllium industry has already implemented a Product Stewardship Program to assist companies processing beryllium and beryllium-containing materials to reduce workplace exposures and minimize potential risks to workers. The **Be Responsible** program (www.berylliumsafety.eu) promotes best practices and employs an exposure level of **600 ng/m³** inhalable 8h TWA which has been determined to reduce the incidence of CBD.

Conclusion:

The OEL of **600 ng/m³** inhalable 8h TWA proposed for the transitional period should be adopted as the final OEL, as it is **protective of workers, economically and technically feasible.**

European Commission
Directorate-General for Employment,
Social Affairs and Inclusion

Brussels, 04 June 2018

Ref: Comments to the European Commission's proposal for the 3rd amendment of the Carcinogens and Mutagens Directive and accompanying socio-economic impact assessment from a procedural perspective

Dear Sir, Madam,

Introduction

BeST - Beryllium Science & Technology Association – represents the suppliers of beryllium metal and beryllium containing alloys in the EU market and has the objective of promoting sound policies, regulations, science and actions related to the use of beryllium as well as promote good practices in the workplace, in order to protect workers handling beryllium containing materials.

The comments below reflect BeST's views in reference to the European Commission's proposal for the 3rd amendment of the Carcinogens and Mutagens Directive (CMD) and the accompanying Commission Staff working document impact assessment (IA) from a procedural perspective. These comments should be read in conjunction with the technical comments concurrently submitted by BeST.

Comments:

1. BeST supports the implementation of a harmonized EU Binding Occupational Exposure Limit (BOEL) for beryllium as one of the implementable preventive measures with the objective of protecting health of workers from occupational diseases, however BeST has unfortunately identified various procedural flaws throughout the socio-economic impact assessment (SEIA) which effects the procedure for establishing the BOEL.
2. BeST notes the lack of transparency from not publicly disclosing the final impact assessment prepared by the external consultant and instead issuing a Commission staff report of the impact assessment (IA) with the proposal.
3. To the point, the published IA refers to a draft version of the SEIA (or at least parts of it) as clearly demonstrated on page 82 of the published document where, referring to face-to-face meetings, it states *"One face-to-face meeting was carried out with the Beryllium Science and Technology Association (BeST), and one more meeting is planned for the 22nd of January 2018"*. BeST confirms to have attended this meeting on the 22th January 2018 and, considering the use of the future in the sentence above, wonders if the data provided since this date have been taken into account.
4. Moreover, in occasion of the first meeting, BeST was informed that the SEIA would feature a sensitivity analysis which however is lacking in the IA.

5. The European Commission refers to the RPA (2018) data throughout the IA. However, this report is not publicly disclosed and therefore its content cannot be verified.
6. Moreover, absent the final version of the SEIA, it is not possible to verify compliance with the requirements established in the Tender Specifications – Call for Tenders N. VT/2017/0005.
7. As an example, BeST is unable to verify, from the content of the IA, that the proposed OEL of 200 ng/m³ – Inhalable Fraction – 8H TWA would not have any effect on EU competitiveness in absence of any indication of current OELs applied outside the EU. The tender specifications explicitly required a description of the different OEL deriving systems in place in EU Member States, EEA countries and in international economic competitor countries (e.g. USA, Japan, Canada, etc.), information submitted by the industry but not included in the IA.
8. Furthermore, according to the content of the IA, all data concerning the adverse health effects associated with the exposure of workers to beryllium is limited to Chronic Beryllium Disease (see as an example Table 2 at pg. 7 of the IA), considered as a non-carcinogenic health affect. In absence of any data concerning the development of carcinogenic health effects associated with the exposure of workers to beryllium, it is unclear why beryllium is still classified as a carcinogen. This is supported by recent studies (Boffetta 2014, 2016), not considered in the IA, that demonstrate that the insoluble forms of beryllium, which are the only forms commercially available in the EU, are not carcinogenic.
9. The IA mentions on page 3 that *“The purpose of this Impact Assessment is to verify, on the basis of available socio-economic data, the robustness of ACSH opinions”*. BeST would like to highlight that the questionnaires sent by the external consultant to Beryllium users, in the frame of the SEIA, were based on three reference values for Beryllium: OEL proposed by the SCOEL (0.02 µg/m³), lowest current national OEL (0.1 µg/m³) and median and mode of national OELs in EU member States (2 µg/m³). They did not include the values proposed by the ACSH for beryllium (0.6 µg/m³ and 0.2 µg/m³ after 5 years). To this extent, BeST does not understand how the methodology for establishing questionnaires enabled the European Commission to verify the robustness of the ACSH opinion, at least for Beryllium.
10. BeST notes that the IA does not analyse the Risk Management Measures in place, the voluntary industry initiatives (e.g. Product Stewardship), Social Partner Agreements, and examples of good/best practices as explicitly required in the tender specifications (page 14, Task 2). BeST has developed and implemented a Voluntary Product Stewardship Program (Be Responsible – www.berylliumsafty.eu) which is not mentioned explicitly in the IA. Voluntary Product Stewardship Programs are mentioned in general on page 16 (*D. Industry Self-Regulation*), but there is no specific analysis by substance.
11. BeST notes that *“an overview of the available standard monitoring methodologies/tools used and their limitations to measure the OELs evaluated with respect to their use”*, as required in the tender specifications (page 14) is not featured in the IA. BeST recalls that measuring beryllium OELs below 0.6 µg/m³ will be very challenging for the industry.
12. BeST also notes that a meeting of the European council is scheduled on 4th June, same date than the deadline to submit comments on the EC proposal. BeST presumes that Permanent Representations need time to analyse the comments of the different stakeholders for the 5 substances included in the third wave and wonders if a such timing enables a sufficient analysis by MS authorities to give their opinions.

13. Overall, the content of the proposal prepared by the European Commission appears questionable given that the IA accompanying such proposal is based on unreliable, scarce or non-existing data, as confirmed on page 19. Moreover, the qualitative assessment conducted by the consultant does not justify the proposed conclusions concerning Beryllium, as demonstrated by BeST in its technical comments, and impact assessments should be conducted and published before and not after the opinion of the ACSH.

We remain at your disposal to discuss the above-points and for any further assistance as necessary.

With high regards
Maurits Bruggink

Maurits Bruggink
Director EU Affairs
Beryllium Science & Technology Association

European Commission
Directorate-General for Employment,
Social Affairs and Inclusion

Brussels 4 June 2018

Dear Sir, Madame,

Introduction

BeST - Beryllium Science & Technology Association – represents the suppliers of beryllium metal and beryllium containing alloys in the EU market and has the objective of promoting sound policies, regulations, science and actions related to the use of beryllium as well as promote good practices in the workplace, in order to protect workers handling beryllium containing materials.

The comments below reflect BeST's views in reference to the European Commission's proposal for the 3rd amendment of the Carcinogens and Mutagens Directive (CMD) and the accompanying Commission Staff working document impact assessment (IA) from a technical perspective. These comments should be read in conjunction with the procedural comments concurrently submitted by BeST.

In brief:

- The identified transitional OEL of 600 ng/m³ Inhalable - 8h time weighted average (TWA) – should be adopted as the final OEL as this level is both protective of workers and technically and economically feasible.
- The IA refers to data sources – RPA (2018) – that are not publicly available thus not allowing stakeholders to verify the legitimacy of the data and the proposed OEL.
- The proposed OEL of 200 ng/m³ – 8h TWA – to be implemented after the transitional period, is unnecessary, infeasible, difficult to measure in all industrial processes, and will have severe and social economic impacts (i.e. loss of jobs in the EU). Many processes are likely to be moved outside the EU - For example, the required use of beryllium as part of the strategic process of recycling of aluminium and magnesium alloys would be negatively impacted affected by the proposed OEL of 0.2 µg/m³.
- The proposed OEL of 0.2 µg/m³ is not aligned with the OELs applied outside the EU such as USA, Japan, China, etc., significantly reducing the EU's competitiveness on international market, as confirmed on page 25 of the IA. The proposed OEL of 0.2 µg/m³ would be 70-90% lower compared to the OELs applied outside the EU.
- The number of workers exposed, the number of identified CBD cases and the number of future CBD cases are grossly overestimated.

Comments:

Introduction

1. BeST supports the implementation of a harmonized EU binding occupational exposure limit (BOEL) for beryllium as one of the implementable preventive measures with the objective of protecting health of workers from occupational diseases. However, BeST has identified several irregularities in the procedure for setting such OEL as well as various erroneous conclusions due to misunderstanding and/or lack of consideration of the data submitted by industry.

Comments on the proposal

2. With regards to the content of the proposal, BeST highlights that beryllium is not classified as a respiratory sensitizer under the CLP Regulation (No. 1272/2008). It is unclear why the European Commission proposes a notation for respiratory sensitization. Therefore, BeST requests that the European Commission does not assign a notation for respiratory sensitization under the CMD.
3. Although classified as a skin sensitizer under the CLP Regulation, BeST notes that the commercially available insoluble forms of beryllium in the EU do not exhibit characteristics of a skin sensitizer. Therefore, BeST requests that the European Commission does not assign a notation for skin sensitization under the CMD.
4. While BeST endorses the identified transitional OEL of 600 ng/m³ Inhalable - 8h time weighted average (TWA) - as this level is both protective and feasible, the proposed OEL of 200 ng/m³ to be implemented after the transitional period is unnecessary, infeasible and difficult to measure in all industrial processes, and will have severe and social economic impacts (i.e. loss of jobs in the EU), especially for the high number of SMEs involved in the beryllium industry. The OEL of 600 ng/m³ inhalable 8h TWA should be adopted as the final OEL, as it is protective of workers, economically and technically feasible, and measurable.
5. In addition, it is unclear why the European Commission has proposed a transitional period of five years for beryllium, given that this period is very short and not sufficient to: (i) evaluate the exposures, (ii) implement risk management measures, (iii) invest in the necessary equipment and (iv) verify the compliance with the proposed OEL. Independently from the duration of the transition period, a significant part of industry will not be able to comply with the OEL of 200 ng/m³ at the current state of art.

Comments on the published impact assessment

6. BeST is aware of the European Commission's practice to publish its own version of the IA and that the content of the IA should mirror parts of the content of the socio-economic impact assessment (SEIA) conducted by the external consultant. However, the IA does not allow stakeholders to verify the legitimacy of the data prepared by the external consultant in support of the proposed OELs and features a significant number of suspected erroneous information.
7. **2.1 What is/are the problems?, Page 3: "For example, exposure to beryllium, in addition to lung cancer, also causes incurable chronic beryllium disease":** BeST would like to note that the most recent epidemiological studies (2014, 2016) by Boffetta demonstrate that the insoluble forms of beryllium, only forms commercially available in the EU, are not carcinogenic.

8. Table 1: Summary of estimates taken forward for the assessment options, page 5:

Carcinogen	Exposure workforce (number of workers)	Typical exposure levels	Major occupational exposure route
Beryllium and inorganic beryllium compounds	54000 Range of 14000 – 74000 depending on which of the three datasets chosen	0.19 µg/m ³ - 2.78 µg/m ³	Inhalation of beryllium – containing dusts and fumes. Dermal exposure is relevant for non-carcinogenic ill-health effects

According to BeST's experience and knowledge of the beryllium industry, the total number of 54000 workers exposed to beryllium is overestimated. This may be due to the use, by the European Commission/external consultant, of an excessively broad interpretation of exposed workers that considers any employee on the site instead of considering only the employees actually exposed to the substance.

Moreover, it is unclear how the European commission has identified the typical exposure levels in a range between 0.19 µg/m³ and 2.78 µg/m³ given that the BeST customer survey conducted in 2015 registered a maximum exposure of 2 µg/m³– Inhalable Fraction.

In addition, dermal exposure is not relevant for non-carcinogenic ill-health effects due to the fact that the insoluble forms available commercially in the EU do not cause any dermal effects, such as sensitization or rashes.

9. Table 2: current and future disease burden related to occupational exposure to carcinogens (number of cases), page 7:

Carcinogen	Health effects caused	Current* disease burden (quantified)	Future** disease burden (quantified)
Beryllium and inorganic beryllium compounds	Chronic beryllium disease (quantified), allergy or asthma symptoms, beryllium respiratory sensitisation, skin sensitisation, cardiovascular, renal, hepatic and haematological effects (not quantified)	3807	4602
<p>*The current disease burden is estimated over the past 40 years</p> <p>**The future health burden is estimated over a 60-year period</p>			

The above table exclusively refers to Chronic Beryllium Disease CBD (quantified), non-carcinogenic adverse health effect associated with exposure to beryllium, and identifies a current disease burden of 3807 cases and a future disease burden of 4602 cases. All other health

effects are not quantified and, in any event, should not be considered as an endpoint for consideration under the CMD. In particular, the commercially available insoluble forms of beryllium in the EU do not exhibit characteristics of a skin sensitizer or of a respiratory sensitizer or cause allergy or asthmatic symptoms.

It is unclear how the number of current and future cases of CBD were estimated given the published data. In absence of any clarification on the above, BeST considers these grossly numbers overestimated. Indeed, BeST survey to health authorities and social insurances in all member states has identified approximately 25 suspected cases of CBD in the last 10 years.

10. **Table 3: National OELs in EU Member States, page 9:**

Carcinogens	Lowest (strictest) national OEL (mg/m ³)	Highest (least strict) national OEL (mg/m ³)	Member States with no OEL
Beryllium and inorganic beryllium compounds	0,00005 PT (Inhalable fraction)	0.05 AT, EL, SK, SI	4 IT, LU, MT, NL

A conversion error is featured in the above table. The highest national OEL is 0.005 mg/m³, i.e. 5 µg/m³, not 0.05 mg/m³.

11. **2.2.3. Diverging national OELs create different competing conditions and protection levels across the EU, pg. 8:** *"PT firms need to comply with an OEL 1000 times smaller (i.e. stricter) than firms in AT, EL, SK..."*: The factor between the lowest OEL and the highest OEL is 100 not 1000, in accordance with the correct conversion factor as stated above.
12. **4:2 Specific Objectives, page 12:** *"To achieve a more balanced protection of workers across the EU against carcinogens while ensuring more clarity and level playing field for economic operators"*: BeST would like to highlight the need to guarantee level playing field with non-EU states as USA, Japan, China, etc. in order to allow the EU industry to maintain as well as enhance its competitiveness at global level.
13. **REACH Regulation, page 13:** *"For the preparation of this impact assessment and for the development of the scientific opinions on the proposed limit values, data from the 'registration' dossiers prepared by manufacturers and importers, as well as data that became available to ECHA's Risk Assessment Committee (RAC)..."*: The Scientific Committee on Occupational Exposure Limits (SCOEL) and not RAC assessed beryllium. Moreover, no conversion factor was applied by SCOEL when assessing US data on beryllium even though different sampling methods apply in the EU and in the US (inhalable versus thoracic or total). We note that such a conversion factor was, instead, taken into account by RAC when assessing substances included in the 4th batch.
14. **G. Guidance documents, page 17:** *"As non-regulatory alternatives, guidance documents or examples of good practice could be developed and disseminated in co-operation with the EU-OSHA..."*: BeST is currently applying to be official campaign partner in the upcoming EU-OSHA campaign on managing hazardous substances at the workplace.
15. **Analytical methods and challenges, page 18:** *"Concerning environmental impacts...such impacts would be minimal"*: BeST would like to highlight that beryllium has no direct adverse impact on the environment. However, beryllium has positive impacts in terms of long-life

duration of electronic and electrical equipment, enables to reduce carbon footprint in automotive by contributing to the recycling of magnesium containing light alloys, and has several applications in electric cars, solar panels, ITER, etc.

16. **Analytical methods and challenges, page 19: “regarding occupational exposure cancer, the available epidemiologic evidence is scarce”:** The recent epidemiologic studies by Boffetta in 2014 and 2016 were not taken into account. Please see comment number 7.

17. **Analytical methods and challenges, page 19: “data on the number of workers exposed is generally scarce and unreliable, and data on the current exposure levels across EU Member**

States is not always available”: It is unclear how the European Commission can substantiate its proposal for an OEL of 600 ng/m³ inhalable 8h TWA, subsequently lowered to 200 ng/m³ inhalable 8h TWA, in absence of any available and reliable data.

18. **Page 23 – “there is a lack of published data for the monetization of chronic beryllium disease”:** It is unclear how the European Commission can evaluate the monetary effects of the proposed OEL for beryllium in absence of any published data.

19. **Table 8: Baseline scenario over 60 years for beryllium and inorganic beryllium compounds, page 24**

Types of health effects caused	Chronic beryllium disease (quantified), allergy or asthma symptoms, beryllium respiratory sensitisation, skin sensitization, cardiovascular, renal, health and haematological effects (not quantified)
No. of exp. Workers	54071 (excluding construction sector)
Change in exposure levels	Past: -3% per year Future: expected 2% per year reduction
Current disease burden (CDB) – no. of chronic beryllium disease cases	Exposure in sectors considered in this study over past 40 years: 3807
Future disease burden (FDB) – no. of chronic beryllium disease cases	3068-4602*
Exp. No. of deaths (FDB) from chronic beryllium disease	307-460*
Monetary values FDB from adverse health effects	EUR 290 million – EUR 1.9 billion
Based on RPA (2018)	
*Workforce turns over at 5% p.a.	

It is unclear how the total number of expected deaths from CBD have been determined as well as the monetary values given the “**lack of published data for the monetization of chronic beryllium disease**”.

Please refer to comments n. 8 and 9 in reference to the number of exposed workers, current disease burden and future disease burden.

20. **Baseline, page 23: “As such, these regulatory mechanisms are not imparting any direct impact on worker exposures”:** Following the Risk Management Option Analysis conducted by the German Authority in the frame of REACH, BeST has developed its Voluntary Product Stewardship

Programme “Be Responsible” to enhance the protection of workers. Therefore, REACH does have an impact on worker protection.

21. **Impacts of the policy options, page 24: “There are about 5800 companies”:** BeST believes that this number is overestimated and it is unclear how it was determined. An estimate based on the input from BeST members indicates a significantly lower number of companies in the EU.

22. **Impacts of the policy options, page 25: “Stakeholders have expressed doubts about the feasibility for certain processes to achieve exposure below 0.2 µg/m³ and that these processes could move outside the EU if a lower OEL is set”:** BeST highlights that the data it submitted to the external consultant and included in the IA (page 111 – Table 50) demonstrates that a

significant number of processes would not be feasible at 0.2 µg/m³ or would require advance controls not economically feasible for companies. All these processes are likely to be moved outside the EU. For example, the required use of beryllium as part of the strategic process of recycling of aluminium and magnesium alloys would be negatively impacted by the proposed OEL of 0.2 µg/m³.

23. **Impacts of the policy options, page 25: “international competitiveness should not be affected”:** BeST does not agree with this statement as the proposed OEL of 0.2 µg/m³ is not aligned with the OELs applied outside the EU such as USA, Japan, China, etc., significantly reducing the EU’s competitiveness on international market, as confirmed on page 25 of the IA. The proposed OEL of 0.2 µg/m³ would be 70-90% lower compared to the OELs applied outside the EU.

24. **Impacts of the policy options, page 25: “there is no impact on employment for an OEL starting with the lowest feasible OEL of 0.2 µg/m³”:** Please see comment number 22. The phase out of various processes and small companies will inevitably have a severe impact on employment and workers.

25. **Impacts of the policy options, Table 9: Multi-criteria analysis for beryllium and inorganic beryllium compounds, excluding construction, page 25**

Impact	Stakeholders affected	Option 2 ≤0.1 µg/m ³ (Lowest value)	Option 3 0.2 µg/m ³ (ACSH)	Option 4 0.6 µg/m ³ (Highest value, ACSH transition value)
Economic impacts				
Compliance costs	Companies	> €1 billion	€130 million	€40 million
Company closures	Companies	Significant impact	No impact	No impact

Transposition and enforcement costs	Public sector	Limited costs 95% of MS would have to transpose	Limited costs 80% of MS would have to transpose	Limited costs 80% of MS would have to transpose
Benefits from reduced ill health	Reduction in CBD cases	2 800 -3 100	2 400	1 600
	Employers	Moderate > €17 million	Moderate €15 million	Moderate €10 million
	companies	Significant positive Reduction of highest OEL/lowest OEL ratio from 50 to no difference	Significant positive Reduction of highest OEL/lowest OEL ratio from 50 to 6	Significant positive Reduction of highest OEL/lowest OEL ratio from 50 to 6
Single-market: consumers	Consumers	Limited impact		
Simplification	Companies	Significant positive % of MS currently above the OEL: 95%	Significant positive % of MS currently above the OEL: 80%	Significant positive % of MS currently above the OEL: 80%
Specific MSs/regions	Member States	Significant AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, EL, HU, IE, LV, LT, PL, RO, SK, SI, ES, SE, UK, plus IT, LU, MT, NL, PT	Significant AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK plus IT, LU, MT, NL, PT	Significant AT, BE, BG, HR, CY, CZ, DK, EE, FR, EL, HU, LV, LT, RO, SK, SI, SE, UK plus IT, LU, MT, NL, PT

Health and social impacts				
Deaths avoided	Workers & families	Significant 270 - 302	Moderate 223	Moderate 150
Ill health avoided including intangible costs	Workers & families	> €240 million	€200 million	< €140 million
Employment – social cost (salary lost)	Workers	Moderate €17 – 180 million	None	None
Environmental impacts				
Environmental releases		All		Neutral impact
<i>Based on RPA (2018);NB: a transition period was not considered in the analysis</i>				

Please see comments n. 22 and 24 concerning the impact of the OEL of 0.2 µg/m³ on companies.

Please refer to comments n. 8 and 9 in reference to the number of exposed workers, current disease burden and future disease burden.

BeST highlights that option 4 is already sufficiently protective of workers as well as technically and economically feasible. Option 3 does not produce any additional beneficial effects to workers and would only translate in additional and unnecessary burden for industry as well as phase out of processes with consequent loss of jobs.

26. **Table 9 – Multi-criteria analysis for beryllium and inorganic beryllium compounds, excluding construction, page 26:** BeST finds the information on number of deaths avoided (between 150 and 302) to be questionable and overestimated as there is no data to support this number.
27. **Comparison of the preferred policy option, page 26: “A notation for dermal and respiratory sensitisation is therefore recommended”:** The commercially available insoluble forms of beryllium in the EU do not exhibit characteristics of a skin sensitizer or of a respiratory sensitizer or cause allergy or asthmatic symptoms.
28. **Impact on SMEs, page 41: “The most significant costs are foreseen for SMEs dealing with formaldehyde and beryllium. However, costs for SMEs remain well below 1% of their turnover, and no SMEs closures or employment effects re expected at the proposed OELs”:** BeST highlights that the proposed OEL is extremely challenging for SMEs and implies advance controls

not economically feasible. Most of these SMEs will have to interrupt their handling of beryllium with consequent closure of sites and unemployment of workers, given that a high number of processes will likely be moved outside Europe. The difficulties in the implementation of the proposed OEL is also confirmed in Annex 2 by the Employers Interest Group in the comments submitted during the Social Partners Consultation and by table n. 50 at page 111 of the IA.

29. Annex 4, Table 27, The effects of the disease, page 73 – Mortality Rate

Endpoint	MoR (years)
Chronic beryllium disease	10%
Source: RPA (2018)	

BeST finds the information on the mortality rate to be questionable and overestimated as there is no data to support this rate.

30. Annex 4, Table 28, Treatment period, page 74 – Treatment period

Endpoint	Treatment period (years)
Chronic beryllium disease	30
Source: RPA (2018)	

BeST finds the identified treatment period (30 years) to be questionable and overestimated as there is no data to support this number.

31. Annex 4, Consultation exercise, page 80-81 – Targeted Online Questionnaires: “Questionnaire 1 was aimed at companies whose workers were exposed to cadmium and its organic compounds, beryllium and its organic compounds ...”: BeST notes that the mentioned questionnaire featured, in Section C entitled "Compliance with a potential new OEL under the CMD", considered the following OELs:

1. Lowest technically feasible 8h TWA
2. lowest economically viable 8h TWA
3. OEL of 2 µg/m³
4. OEL pf 0.1 µg/m³
5. OEL of 0.02 µg/m³

It is unclear how the above-mentioned questionnaire was able to assess the implications of the proposed OELs of 0.6 µg/m³ and 0.2 µg/m³, both not present in the questionnaire, as well as identify the lowest economically or technically feasible 8h TWA. Moreover, there is no data on the number of companies that have replied to the questionnaire in the IA.

32. Annex 4, Face-to- face meetings and additional conference calls, Page 82 – “one more meeting is planned for 22nd January 2018”: The IA does not reflect the final data and conclusions submitted to the European Commission by the external consultant but reflects a draft report, or at least parts of it, submitted by the external consultant to the European Commission before 22 January 2018. BeST would consider this information outdated and therefor unreliable. Moreover, BeST submitted additional information after the meeting of 22 January 2018 and has no confirmation that such data was taken into account.

33. Annex 7, Table 51: Sectors, and the group processes predominantly used, page 121:

Sector	Chemical	Thermal	Mechanical	Melt	Alloys
Foundries	N	N	N	Y	
Metal fabrication	N	N	Y	N	
Transportation	Y	Y	Y	Y	Cu-Be alloys BeO Al-Be alloys
ICT	Y	Y	Y	N	Cu-Be alloys (typically 0.2-2% Be metal)
Specialist manufacturers	Y	Y	Y	Y	Cu-Be alloys Ni-Be alloys BeO Be Al-Be

Medical devices	Y	Y	Y	N	Be metal Cu-Be alloys Be foil BeO
Glass	Y	Y	Y	Y	?
Construction	N	N	Y	N	?
Laboratories	Y	N	N	N	?
Recycling	N	N	Y	Y	ALL

Source: RPA and BeST

BeST would like to clarify that the last column of the above-table should be entitled “Beryllium containing materials” and not “alloys”, given that Beryllium Oxide is not an alloy but a ceramic. In addition, (i) BeO is used in ICT and (ii) only anecdotal uses of beryllium salt are present in the laboratories sector.

Moreover, BeST reiterates that it is not aware of any beryllium being supplied to the glass or construction industry but only of its presence as a naturally occurring element in raw materials. This information was submitted to the external consultant but does not appear in the IA.

34. Annex 7, Table 53, page 122: Sectors in the EU affected by beryllium and any available average exposure concentrations in $\mu\text{g}/\text{m}^3$:

Sector	MEGA 95 th percentile	France 90 th percentile ¹¹⁷
Foundries	1.05 (n=101)	16.06 (n=159)

Metal fabrication	0.228 (n=79)	0.6 (n=76)
Transportation	0.554 (n=14)	0.015 (n=14)
ICT	0.512 (n=33) *	10.44 (n=29)
* Specialist manufacturers	0.512 (n=33) *	-
Medical devices	0.512 (n=33) *	0.5 (n=74)
Glass	2.78 (n=16)	-
Construction	2.52 (n=10)	-
Laboratories	0.512 (n=33) *	-
Recycling	0.19 (n=116)	0.1 (n=30)
<i>Source: RPA, MEGA, France 2004-2006 - Vincent et al.</i>		
<i>Note: * The value has been taken from the category 'other sectors' in the database</i>		

The 90th percentile is not the most relevant statistic data to describe the exposure situation. The median, mean or geometric mean are not taken into account even though more realistic. As an example, the Vincent et Al study indicates a median and geometric mean of approximately 0.5. In absence of a column indicating the geometric mean and/or median, the above-mentioned table is biased and not reflective of reality.

Moreover, the exposure levels expressed for glass and construction are questionable.

35. **Annex 7, Estimated EU workers exposed, page 124:** *"it seems likely that BeST has included the companies that it supplies and their workers, but has not allowed for the companies that are further down the supply chain"*: Please see comments n. 8 and 22.
36. **Annex 7, Estimated EU workers exposed, page 126:** *"Both the BeST and EU-OSHA predictions are for 8% of workers being exposed to 2 µg/m³ or more"*: BeST questions the simplistic approach applied to determine such number. BeST members conducted a survey to their customers in 2015 and no company was above 2 µg/m³ inhalable. This survey has been provided to the external consultant.
37. BeST highlights that Beryllium is a critical raw material (CRM) for the EU. Beryllium and its alloys are essential and non-substitutable in a wide range of strategic sectors - as confirmed on page 25 of the IA - such as aerospace, energy, automotive, medical, electronics, and defence. Owing to its superior properties, the use of beryllium is driving growth. An overly restrictive OEL would be contrary to this CRM status, granted by the European Commission for economic importance and supply risk reasons.
38. Moreover, the beryllium industry has already implemented a Voluntary Product Stewardship Program to assist companies processing beryllium and beryllium-containing materials to reduce

workplace exposures and minimize potential risks to workers. The Be Responsible program (www.berylliumsafety.eu) promotes best practices and employs an exposure level of 600 ng/m³ inhalable 8h TWA which has been determined to reduce the incidence of CBD.

Conclusion:

The OEL of **600 ng/m³** inhalable 8h TWA proposed for the transitional period should be adopted as the final OEL, **as it is protective of workers as well as economically and technically feasible.**

*We remain at your disposal for any further enquiries

With high regards

Maurits Bruggink

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Director EU affairs

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