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April 15, 2015

***Technical Barriers to Trade (TBT) Inquiry on Proposed German Regulations on Beryllium***

As the free world's only fully integrated "mine-to-mill" producer of beryllium-based products, Materion Corporation is very aware that Germany's Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), the German competent authority under Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), is suggesting European-wide regulation of beryllium by placing it on the REACH Candidate List as a Substances of Very High Concern. The BAuA is also recommending a derived no effect level (DNEL) as the occupational exposure limit (OEL) for beryllium of  $0.06 \mu\text{g}/\text{m}^3$  as part of its recommendation.

Materion realizes this regulatory initiative is not at the stage of a technical regulation, but we are certain these actions by Germany will adversely impact the beryllium marketplace in Europe and the rest of the world. If Germany is successful in establishing a REACH regulation restricting beryllium-containing materials in either Germany or the European Union (EU), it will create a significant and insurmountable barrier to trade between the U.S. and Europe.

Materion believes that the path recommended by Germany is not the optimum approach and suggests that the most reasonable and balanced outcome of the RMOA process is not authorization or restriction. Our research to practice experience supports the viable option of having the German authorities adopt the evidence based OEL of 0.2 micrograms beryllium per cubic meter ( $\mu\text{g}/\text{m}^3$ ) along with risk management measures that have been shown to be effective in protecting workers from chronic beryllium disease (CBD).

Europe does not have its own supply of beryllium. There is no beryllium mining in Europe. Approximately 75% of Europe's beryllium supply comes from the U.S. Given the importance of the beryllium-containing materials to the European defense, aerospace, automotive, fine watch, energy and electronics industries and its importance in emerging technologies and innovation [Critical Uses of Beryllium](#), we are interested in sharing our views on the matter and would welcome further opportunity to comment and participate in Germany's public consultation on this matter.

On September 22, 2014, Germany's BAuA sent a letter to the beryllium industry and related associations informing them of the results of their evaluation under REACH of beryllium metal. BAuA indicated that an EU-wide regulation has to be considered and suggested beryllium be placed on the REACH Candidate List as a Substance of Very High Concern (SVHC) followed by an inclusion on the list of substances whose use requires specific authorization. The actions by the German BAuA are the first steps toward possible restrictions, severe manufacturing limitations and an overall blacklisting on the uses of beryllium in the EU. The REACH Candidate List is considered to be a global blacklist.

On March 19 2015, BAuA held a stakeholder meeting in Dortmund, Germany to obtain input from the German Small and Medium-sized Enterprises (SMEs) who filed comments opposing the recommendations of the BAuA. The BAuA was surprised by the attendance of additional representatives of the large industry associations [Bundesverband der Deutschen Industrie e.V.](#) (BDI), the German Automotive Association (VDA) and by the attendance of representatives from Volkswagen and Airbus.

### Clarification Questions

#### **1. Does Germany have a substitute material for beryllium and an alternative competing material?**

If Germany were successful in achieving the intended outcomes of its actions on beryllium, the impact on US beryllium trade with Germany and the rest of the EU would be substantial. It would also have an adverse ripple effect with other non-EU trading partners and would threaten the supply of this strategic and critical material. Is Germany seeking to restrict the trade and use of this material in critical applications for aerospace, automobiles, medical technology, consumer electronics, telecommunications and defense systems in order to promote a competing material that is produced or used in Germany as an alternative to beryllium?

#### **2. Why is Germany recommending unnecessary trade restrictions on beryllium, a critical material?**

There is no mining and production of beryllium in the EU and the reality is that most beryllium comes from the US where it is classified as the only material both “strategic” and “critical” to the US Department of Defense. The EU has also designated beryllium as a “critical” material because of its economic importance within the EU. European assessments on the criticality of beryllium all state that due to its unique combination of properties beryllium cannot be readily substituted, and where it is possible, the substitutes will inevitably show a loss in performance. [Beryllium: A Critical Material Assessment](#)

Both commercial and defense critical systems depend on an unfettered supply of beryllium containing materials. The beryllium industry’s scientific position is supported by the automotive, aerospace, security and defense, and metals associations in Germany.

Placing beryllium on the REACH candidate list, placing REACH restrictions, or implementing an overly restrictive and scientifically unjustified OEL could essentially remove 75% of Europe’s beryllium supply that is sourced from the US – a reliable and friendly trading partner. These trade restrictions seem illogical when countries around the world are focusing on how to acquire and maintain supplies of critical materials needed for today’s technological advances. Why would Germany risk losing its supply of this critical material by blacklisting beryllium?

#### **3. The German BAuA chose to use a non-transparent process over a transparent and open process inclusive of other Member States and affected stakeholders. Why?**

The German BAuA recommendation to place beryllium on the REACH Candidate list was totally shielded from input from other Member States and was not transparent to the industries that depend on the unique properties of beryllium in the products they produce. The BAuA could have chosen to issue a draft decision, reach out to other Member States, and seek stakeholder input prior to finalizing its evaluation. Instead, it chose to publish the evaluation absent input from other Member States and stakeholders. Other Member States have led REACH-related evaluations of other substances whose potential regulatory restrictions would have affected their EU and international trading partners. Many of them elected to solicit information from these countries and conducted meetings with stakeholders that might be adversely affected early in the formulation of a

recommendation. Germany's trading partners deserve a detailed explanation relative to the lack of transparency, its motivation for excluding other Member States and its apparent unwillingness to accept the scientific and technical expertise and real world experiences offered to them by the producers and users of a critical material.

**4. Germany did not consider the impacts on SMEs in its recommendation and has not publically announced any plans to actively work with stakeholders toward a mutually acceptable solution. Why?**

It appears that Germany did not consider the impacts on small and medium-sized enterprises, German and EU security interests, high-performance technologies dependent upon beryllium, and public health and safety. During meetings with economic ministers in the States of Baden-Württemberg, Bavaria, and North-Rhine Westphalia, they indicated they understand the problems posed for industry and SMEs, in particular, of overregulation in Germany as well as in other EU countries. During the stakeholder meeting in Dortmund, the SMEs in attendance clearly objected to the proposed DNEL, listing of beryllium on the Candidate List or initiating REACH restrictions. The consensus of those attending the meeting suggested that there was little hope that there would be any changes in the position of the BAuA even though BAuA stated no decision on how to proceed had been made. There was no commitment or formal invitation by the BAuA toward further discussions with stakeholders either individually or separately. On the contrary, BAuA stated another meeting could occur later this year, but only to present the decision of the BAuA on its risk management option analysis (RMOA). It is obvious that the lack of meaningful stakeholder involvement resulted in an incomplete evaluation report. Germany needs to provide an explanation as to why full transparency and engagement of stakeholders in the development of a risk management option is not in the best interests of its trading partners.

**5. Materion and other beryllium industry representatives were informed that the BAuA had developed a draft RMOA even before the stakeholder consultation occurred. Does Germany plan to reconsider its recommendations based on its evaluation?**

Germany's conclusion to place beryllium on the REACH Candidate List and to promote an extremely low OEL is premised on numerous technical errors and omissions in its evaluation. Due to these errors, many stakeholders have called for a restart of the beryllium evaluation. The evaluation report carries the following disclaimer: *"The agency does not guarantee the accuracy of the information included in the report."* [Beryllium Substance Evaluation Report](#) The recommendations as currently proposed are not acceptable. A willingness to correct the technical errors and arrive at an outcome that is protective of workers and does not result in trade barriers or economic hardships is requested.

**6. Can Germany support an alternative recommendation for beryllium?**

As an alternative to listing on the REACH candidate list, initiating restrictions and the adoption of an unrealistic and unsupportable OEL, the beryllium industry has been advocating an OEL of 0.2 µg/m<sup>3</sup> that should soon be adopted in the US, and is currently the limit in Spain, Ireland and Poland. [Industry-Labor letter to OSHA re Model Beryllium Standard 2012](#) This limit has been proven to be appropriate through numerous scientific studies conducted by the US National Institute of Occupational Safety and Health (NIOSH) and other scientific institutions in the US. [Perspectives on Establishing a Beryllium OEL](#) No comparable scientific studies have been conducted in European operations where beryllium-containing materials are used. The most recent scientific

evidence should be fully reviewed and considered by all interested stakeholders prior to making any final regulatory decisions. An alliance of many industrial entities in the EU has formed and developed a position on alternatives to REACH Authorization. Their position paper states: [Cross Industry Recommendations for Better Regulation in Chemicals Management](#)

“In our view, it is not in the best interest of society if the Commission were to continue down a path that would opt for authorisation as a risk management option **where potential risks can be more effectively addressed by workplace-specific legislation**. Such legislation better addresses potential risks at the workplace as it also ensures the safety of employees working with intermediates (which fall outside the scope of REACH Authorisation). **REACH Authorisation does not add any layer of protection** compared to the level of safety that can be established by applying occupational health and safety legislation, and by establishing a protective EU-wide occupational exposure limit (OEL).”

Materion respectfully requests a thorough investigation and logical explanations for Germany’s current actions advocating strict regulation of beryllium that would be damaging to Materion, US trade with Germany and the EU, SMEs and beryllium-dependent industries whose technologies and innovation in the EU are in jeopardy.

Please note that all URL linked documents have also been included as separate documents with this inquiry.

Thank you.

A handwritten signature in black ink that reads "W. Glenn Maxwell". The signature is fluid and cursive, with the first name "W." and last name "Maxwell" clearly legible.

Glenn Maxwell

## Addendum

### **I. Purpose of Risk Management Options Analysis (RMOA)**

Presented herein were options proposed by the European Beryllium Science and Technology Association (BeST) to the BAuA for consideration on the risk management options analysis of beryllium. BeST represents the suppliers of beryllium in Europe, as well as traders and industries who use beryllium. Materion is a member of BeST. The options were directed toward protection of workers as the primary concern and offered a reasonable and balanced outcome of the RMOA. Materion primarily developed the recommendations creating a reasonable path forward that both provides for worker safety and preserves the supply of beryllium to the economies of the EU and the US.

As EU authorities have emphasized, the RMOA is supposed to find the best risk management option, which includes alternatives to authorisation and restriction. It is the understanding of Materion that this process has been introduced in order to involve stakeholders and increase the transparency of REACH. It follows that beryllium should not be identified as an SVHC and put on the REACH Candidate List. The risks pertaining to the use of beryllium are essentially a matter of occupational health and safety. The BAuA's [Beryllium Substance Evaluation Report](#) verifies this assessment.

### **II. Substance Evaluation Conclusions by Germany May Have Been Influenced by Outdated Information**

The substance evaluation that the BAuA now relies upon to construct its risk management analysis contained numerous errors. The BAuA was advised of these errors via the document [BeST Response to Stakeholder Consultation Supplement](#). Of primary concern to Materion was the highly erroneous conclusion by the BAuA that there was a high level of concern relative to the health of workers exposed to beryllium. The BAuA concluded that exposures were not well controlled and that 65,000 workers were exposed to beryllium. The BAuA report stated there were 2,435 workers from the Czech Republic exposed to beryllium. Information provided to BeST by authorities in the Czech Republic, however, indicates only 85 workers are exposed to beryllium and they ranked these workers in the lowest risk categories. Similarly in Poland, the report stated 3,577 workers are exposed to beryllium, while the Polish authorities have stated only 126 workers are exposed. The beryllium industry is concerned that the number of exposed workers is greatly overestimated. The industry is continuing to collect accurate and useable information for eventual submission to the BAuA.

Also, Materion learned that the European Commission placed a contract on July 23, 2014, with Kooperationsstelle Hamburg IFE GmbH for €370,745 to:

*“carry out a number of identified tasks, including the development of a model to generate estimates of occupational exposure to hazardous chemicals in Europe and to design a web-based tool to allow interested stakeholders to access and use this exposure data for risk management measures at enterprise level and for improving occupational health, for example by setting priorities for prevention, regulatory risk management, as well as occupational disease recognition at national and European level.”*

The call for tender also stated that the CAREX system, which was used to complete the Community Rolling Action Plan (CoRAP) evaluation under REACH on beryllium: *“is based on exposure workforce statistics from 1990*

*– 1993, and the exposure prevalence information is even older, and therefore outdated; The initial database is only based on Finnish and United States of America exposure prevalence data, which was used by national experts to estimate exposure in the 15 EU Member States at that time, and 4 countries out of the 10 which joined the EU in 2004; The database does not contain any information on exposure trends over time.”*

The call for tender by the European Commission confirms Germany’s evaluation of beryllium is based on outdated data and estimates. Materion also learned from discussions with the Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA) in a meeting on November 13, 2014, that the German worker exposure data set being used by the BAuA to support its opinion that “*exposures are not sufficiently controlled*” is comparing its DNEL value to an exposure dataset where about 80% of the data appears to be below a limit of analytical detection that is higher than the proposed DNEL. [Beryllium Exposures IFA](#) Such a mischaracterization of the IFA data by the BAuA is inaccurate, inappropriate and more importantly a gross disservice to workers by implying a widespread beryllium risk exists in Europe.

It is an interesting side note that Germany has not had an OEL for beryllium for over a decade, whereas the majority of countries utilize an OEL of between 0.2 and 2.0 micrograms per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ). The data being collected by the beryllium industry is clearly showing that the prevalence of Chronic Beryllium Disease (CBD) in other member states is basically non-existent. This suggests that establishing and enforcing a technologically and economically feasible OEL can be supported as a viable risk management option. In contrast, the BAuA states that Germany has 2-3 cases of CBD per year which can support the CBD case rate in Germany is most likely due to the complete absence of an OEL and other enforceable workplace practices in Germany for over a decade.

The BAuA also suggests high exposures to beryllium are occurring in several manufacturing sectors. The manufacturing experts within Materion believe that many of the industries cited by the BAuA are not associated with beryllium-containing products manufactured by the industry. Instead, they more likely are due to naturally occurring beryllium, an element that is found at low concentrations in numerous materials and products. Most mineral and clay-based products contain small quantities of beryllium, which may account for the detection of beryllium in manufacturing sectors which do not utilize commercial beryllium-containing products. Common examples include concrete, wall board and ceiling tiles, detergents, fertilizers, food stuffs, mineral abrasives, etc. In fact, the highest levels in the German IFA data were associated with foundries and construction. BeST, which represents 100% of the beryllium market in the EU, does not sell into the construction industry and it is not aware of any downstream usage. Materion experts believe that alleged exposures in construction are all the result of beryllium occurring naturally in soil or construction materials. Obviously, the BAuA would not want to proceed with a risk management option that could adversely impact the construction industry and millions of jobs in the EU. Likewise, Germany’s proposed regulation of beryllium should not disrupt the trading of beryllium-containing commodities and products between the US, Germany and the rest of the EU.

### **III. Wrong Safety Factor Was Used to Derive No-Effect Level (DNEL)**

The derivation of the DNEL by the BAuA was not performed in a fashion that incorporated the current state of scientific knowledge and was not in accord with the guidance provided by the European Chemicals Agency (ECHA).

The BAuA correctly uses the Lowest Observable Adverse Effect concentration (LOAEC) of  $0.2 \mu\text{g}/\text{m}^3$  identified in several key epidemiologic studies as its starting point for a long-term systemic DNEL calculation. However, the BAuA applied a factor of 3 to derive a No Observed Adverse Effect Concentration (NOAEC) resulting in a DNEL of  $0.0666 \mu\text{g}/\text{m}^3$ , which it then rounded to  $0.06 \mu\text{g}/\text{m}^3$ . The BAuA stated no additional factor is needed since CBD is observed among already sensitive individuals. However, the assumptions made and the determination on the need to apply an additional safety factor of 3 is contradicted by ECHA in its document [ECHA Guidance on DNELs](#) which states:

*“Human data are valuable as a source of hazard information because they apply directly to the human species, and the mode of action (MoA) is usually relevant. As a consequence, no inter-species assessment factor is needed when human data are used for derivation of DNEL/DMEL. Furthermore, human data have in most cases been obtained from relevant exposure conditions and are based on an adequate route of exposure. In addition, human data most often come from studies covering a more heterogeneous sample of the population than animal studies carried out on inbred strains.”*

A reasonable interpretation of the above guidance leads to a scientifically supportable conclusion that it is inappropriate to divide the LOAEC by a factor of 3 to obtain a DNEL for beryllium. Since the LOAEC was derived from diverse studies of the most sensitive human populations a safety factor of 3 need not apply. Had Materion’s experts been involved in the deliberations regarding the substance evaluation, they could have provided the BAuA with a unique opportunity for understanding the evidenced-based information regarding an appropriate OEL.

The willingness of Materion to share its expert knowledge and experiences led to the development of a model agreement in the United States between industry and labor toward protecting workers and protecting jobs. The agreement was offered to the U.S. Occupational Safety and Health Administration to serve as a basis for a beryllium OEL of  $0.2 \mu\text{g}/\text{m}^3$ . The agreement was also offered to the BAuA as part of the industry submission.

#### **IV. Misinterpretation of the Relevant Data Led to Errors in Derivation of the DNEL Proposed by the BAUA**

Since 1998, the U.S. National Institute for Occupational Safety and Health (NIOSH) and Materion have participated in a formal joint research partnership to study the best ways to protect beryllium workers. Over 75 studies have been published as part of this joint research collaboration. As a result of this joint research partnership, the underlying data sets used in the various studies are available to all authors. A 2012 study [Schuler 2012 Beryllium Study](#) provides the only complete dose response analysis for CBD. Table 2b in the 2012 paper lists the average, cumulative and highest job values defining the lowest exposure at which CBD was observed. This data is based on using the total mass closed face cassette air sampling method, not the inhalable air sampling method common throughout the EU. Table 2b also shows that 34.4%, 43.8% and 33.2% of the study population were exposed below the average, cumulative and highest job values defining the lowest exposure at which CBD was observed. What is not stated in the paper, but is available from the underlying dataset, are the NOAEC values for that portion of the study population exposed below the LOAEC. The following information summarizes the LOAEC and NOAEC for the Schuler 2011 study.

##### *For Average Total:*

The lowest exposure at which CBD WAS observed was  $0.200 \mu\text{g}/\text{m}^3$  (LOAEC).

The highest value at which CBD WAS NOT observed below the latter was  $0.199 \mu\text{g}/\text{m}^3$  (NOAEC).



*For Highest-job Total:*

The lowest exposure at which CBD WAS observed was 0.216 µg/m<sup>3</sup> (LOAEC).

The highest value at which CBD WAS NOT observed below the latter was 0.214 µg/m<sup>3</sup>. (NOAEC).

Had Materion known the BAuA was attempting to derive a DNEL for CBD, we would have provided this expert information to assist the BAuA in their understanding of the most current scientific information. Subsequently, Materion provided the BAuA with a statement from NIOSH's scientific expert with the above information, which provides a substantive scientific justification for the BAuA to change its recommendation for a DNEL to 0.2 µg/m<sup>3</sup>. The BAuA should embrace the expert analysis by Schuler.

**V. The BAuA's Determination of a DNEL Failed to Consider the Impact of Sampling Methodology**

It is very important to note that the US studies used to set the scientifically supported 0.2 µg/m<sup>3</sup> value utilized a sampling method that is commonly referred to as total beryllium closed face cassette (CFC) method while Germany and most other EU countries have standardized on a sampling method referred to as the inhalable method. In short, studies have repeatedly found that the two methods differ by a factor of 3 or more with the inhalable method collecting three or more times more mass than the total CFC method when sampling is done in the same exact atmosphere. The difference in sampling results was recognized by the BAuA as a footnote at the bottom of Table 30, but was not addressed in the derivation of the DNEL value. Based on the best scientific evidence, a 0.2 µg/m<sup>3</sup> NOAEC should actually translate to a 0.6 µg/m<sup>3</sup> OEL or 0.6 µg/m<sup>3</sup> DNEL. A beryllium-specific study of this difference in the EU has been completed by the Fraunhofer Institute ITEM and was published in a peer reviewed scientific journal. [Beryllium Sampling Comparison Study Fraunhofer](#). The data was provided to the BAuA in advance of the study being published. Had Materion's experts been allowed to work in concert with the BAuA, they would have suggested that the evaluation not be finalized until this comprehensive and significant study was completed.

**VI. The German BAuA initially decided to conduct an evaluation of beryllium metal based on its current classification. Finding that the current classification is wrong for a number of endpoints and considering that the most recent scientific evidence clearly shows that beryllium metal does not cause cancer in humans, why would the BAuA not use this information to validate not listing beryllium on the REACH Candidate List?**

Germany and the EU should adopt a harmonized classification of beryllium metal to reflect the most recent science so that workers are informed of the true risks associated with exposures to beryllium metal. The current classification of elemental beryllium applied without distinction to beryllium metal has been found to be deficient in a number of endpoints, particularly cancer, and, therefore, misleads workers. Workers deserve to know the true risks associated with a substance so that they can ensure that they can take the measures necessary to protect themselves and to ensure that their employers provide the necessary protective measures that they are obligated to undertake. The current EU harmonized classification is outdated and based on criteria preceding the Classification, Labeling and Packaging (CLP) Regulation. It does not take into account the form (metallic form) in which the substance is placed on the market and used. Indeed Art. 8(6) of the CLP Regulation requires that *"Tests that are carried out for the purposes of this Regulation shall be carried out on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used."* [Proposal-for-Revision-of-Classification Beryllium Metal.pdf](#)