



## SOCIO-ECONOMIC ANALYSIS

### Of the impacts of non-renewal of Lead (Pb) exemption for test & measurement industrial type products (Category 9) Exemption 13(a) – Annex III

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**SUBSTANCE:** Lead (Pb)

**CAS:** 7439-92-1

**FROM:** Test & Measurement Coalition (TMC)

**INTENDED USE:** in white glasses used for optical applications

**DATE:** 20 January 2023

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## Of the impacts of non-renewal of Lead (Pb) exemption for test & measurement industrial type products (Category 9)

### Exemption 13(a) – Annex III

#### PROJECT TITLE:

Socio-economic analysis of the impacts of non-renewal of Lead (Pb) exemption for the test & measurement industrial type products category 9, Exemption 13(a) – Annex III

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## ABBREVIATIONS

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<b>B2B:</b>	Business-to-Business
<b>CAGR:</b>	Compound Annual Growth Rate
<b>CAR:</b>	Competent Authority Report
<b>COTS:</b>	Commercial Off-The-Shelf
<b>EBIT:</b>	Earnings Before Interest and Taxes
<b>ECHA:</b>	European Chemicals Agency
<b>EEA:</b>	European Economic Area
<b>EEE:</b>	Electrical and Electronic Equipment
<b>EU:</b>	European Union
<b>EUR:</b>	Euro (currency)
<b>NPV:</b>	Net Present Value
<b>Pb:</b>	Lead
<b>PCA:</b>	Printed Circuit Assembly
<b>PCB:</b>	Printed Circuit Board
<b>R&amp;D:</b>	Research and Development
<b>RoHS:</b>	Restriction of Hazardous Substances in Electrical and Electronic Equipment
<b>SAC:</b>	Tin-Silver-Copper
<b>SAGA:</b>	Suitable Alternatives Generally Available
<b>SEA:</b>	Socio-Economic Analysis
<b>SEAC:</b>	Committee for Socio-Economic Analysis
<b>SME:</b>	Small and Medium Enterprise
<b>SnPb:</b>	Tin-Lead
<b>T&amp;M:</b>	Test & Measurement
<b>TMC:</b>	Test & Measurement Coalition
<b>U.S:</b>	United States
<b>UV:</b>	Ultra-Violet
<b>UVA:</b>	Ultra-Violet A
<b>UBM:</b>	Under-Bump Metallisation
<b>WEEE:</b>	Waste from Electrical and Electronic Equipment

## 1. SUMMARY OF SOCIO-ECONOMIC ANALYSIS

### Purpose and methodology

RoHS stands for Restriction of Hazardous Substances and impacts the entire electronics industry and many electrical products. The principal RoHS, also known as Directive 2002/95/EC,<sup>1</sup> originated in the European Union in 2002 and restricted the use of six harmful chemical substances in electric and electronic equipment (EEE), allowed in the EU market. Test & measurement instruments (current Category 9 - industrial) were initially excluded from the scope of RoHS 1. Moreover, **in 2011, the RoHS 1 was revoked and replaced with Directive 2011/65/EU,<sup>2</sup> which is known as RoHS-Recast or RoHS 2. It expanded the scope of products covered in RoHS 1 and imposed new obligations on EEE importers and manufacturers by adding Categories 8 (medical devices) and 9 (monitoring and control instruments).** RoHS 2 included a long transitional period for Category 9 industrial products, extending to mid-2017. On 4 June 2015, the European Commission Delegated Directive (EU) 2015/863<sup>3</sup> amended Annex II of EU RoHS 2, by adding four additional phthalates onto the original list of six restricted substances. Category 9 – Industrial equipment again required an extended transition period before these additional substance restrictions applied in July 2021.

Industrial test and measurement instruments are very different from low-mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test & measurement (T&M) are high mix, low volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans and are made available on the market for at least a decade. In comparison with other categories of equipment in scope of RoHS 2, **category 9 – Industrial equipment contributes a fraction of one percent of the total annual quantities of RoHS substances.**

In line with the **existing official guidance from ECHA on the preparation of the Socio-Economic Analysis,<sup>4</sup> this SEA aims to gather technical and economic information to describe ex-ante in both qualitative and (if feasible) quantitative terms the (orders of magnitude of) socio-economic impacts T&M Coalition members as well as the relevant EEA supply chain and society are expected to face from the non-renewal of the lead (Pb) exemption in white glasses used for optical applications, which would otherwise expire on 21 July 2024.**

<sup>1</sup> Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32002L0095>.

<sup>2</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) Text with EEA relevance. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32011L0065>.

<sup>3</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0863&from=EN>.

<sup>4</sup> The ECHA Guideline for the SEA preparation as a part of Application for Authorization is available at: [https://echa.europa.eu/documents/10162/23036412/sea\\_authorisation\\_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e](https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e) ; The ECHA layout for an SEA to be used in Application for Authorization is available at: [https://echa.europa.eu/documents/10162/13637/sea\\_format\\_with\\_instructions\\_v4\\_en.docx/0cbc5102-6ba2-2170-480a-0061d2798f55](https://echa.europa.eu/documents/10162/13637/sea_format_with_instructions_v4_en.docx/0cbc5102-6ba2-2170-480a-0061d2798f55)

This SEA has been performed by EPPA<sup>5</sup> at the request of Test & Measurement Coalition (TMC), in view of providing regulators with strong evidence-based findings on the expected social and economic impacts that are expected to occur should the use of lead (Pb) be impacted by the non-renewal of the RoHS exemption.

This SEA is based on information and data gathered from the industrial and professional test and measurement equipment manufacturers. **A survey has been conducted**, by providing a detailed questionnaire to gather information and data from actors likely to be affected by a non-renewal of the RoHS exemption in the EU.

**TMC manufacturers of industrial and professional test and measurement equipment have participated in the survey.** The market share covered by this survey represents approximately 70% of the EEA market. The assessment is, therefore, highly representative and can serve as a basis for defining the anticipated socio-economic impacts resulting from the non-renewal of the RoHS exemption.

The participating companies indicated that the exemption 13(a) (Annex III) information reported in this SEA are relevant for the professional, scientific, laboratory, analytical, clinical and industrial applications in numerous products groups. A full list of relevant product groupings and equipment types is provided in the Annex I of this SEA.

TMC members have been carefully instructed to base their statements and estimations as much closer to real data or perception of future changes as possible, so as to have conservative estimates, always putting the protection of the human health and environment upfront.

This SEA covers the safe use of test and measurement equipment, the technical difficulties associated with their substitution via alternatives, the social and economic impacts at different level of the supply chain, and the EU macroeconomic impacts.

### **Main findings**

It is shown that there are currently no suitable lead-free alternatives that meet RoHS exemption criteria on the EU market for test & measurement industrial type products and that **re-designing of the test & measurement equipment could take four to five years per product line**. Hence, losing the ability to apply Annex III, exemption 13(a) when considering RoHS conformity for the associated test and measurement industrial products would entail the development of a fairly large number of new alternative compliant materials as well as the increased costs connected to the redesign, retesting, requalification, and replacement of the assembly process.

Overall, the **total impact of a non-renewal is monetized in the range of 1.2 billion EUR and 1.6 billion EUR** (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of:

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<sup>5</sup> [www.eppa.com](http://www.eppa.com)

- [CONF.] of economic impacts (EBIT loss) for test and measurement industrial type products' manufacturers;
- [CONF.] EUR of substitution costs for test and measurement industrial type products' manufacturers;
- [CONF.] EUR of social impacts (i.e., unemployment in the EU-27).

## 2. AIMS AND SCOPE OF THE SEA

### 2.1 Purpose, scope and methodology of SEA

RoHS stands for Restriction of Hazardous Substances, and impacts the entire electronics industry and many electrical products. The exemptions listed in Annexes III and IV must adapt to scientific and technical progress as defined in article 5 of Directive 2011/65/EU.<sup>6</sup> This application is specifically for the **renewal of Annex III exemption 13(a), concerning lead (Pb) in white glasses used for optical applications**, which would otherwise expire on 21 July 2024.

This ex-ante Socio-Economic Analysis (SEA) aims to identify and to assess in both qualitative and quantitative terms the socio-economic impacts that are expected to occur should this exemption not be renewed (i.e., the likely impacts in the non-exemption scenario as compared to the baseline business-as-usual scenario).

**A survey has been conducted**, by providing a detailed questionnaire to gather information and data from industrial and professional test and measurement equipment manufacturers likely to be affected by a non-renewal of the RoHS exemption in the EU.

The participating companies have provided socio-economic data in view of extrapolating (based on a large total market share) the impacts for the whole market in a conservative approach, as further detailed below. Based on the weight of RoHS substances used in their products, the market share covered by this survey represents approximately 70% of the EEA market. **The estimates reported in this socio-economic analysis should be considered as a minimum (lower bound) of the expected impacts of a non-renewal of Annex III exemption 13(a).**

<sup>6</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) Text with EEA relevance. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32011L0065>.

From a geographical perspective, this analysis focuses on the European Economic Area (EEA) territory, comprising the European Union (EU-27), Iceland, Liechtenstein, and Norway. One has followed “SEAC’s approach to assessing changes in producer surplus”.<sup>7</sup> As there is no alternative available in general (SAGA)<sup>8</sup> to lead (Pb), one has considered a **4-year time horizon for this assessment**, starting from the year 2024, (year of the expiry of the current exemption). In other terms, the SEA accounts for the costs and benefits to the EEA society in the event of RoHS substance is not granted the renewal of the RoHS exemption in test and measurement industrial type products.

Future monetary values (when data were available) have been estimated by using the concept of net present value (NPV), adopting a 4% annual discount rate, which is the standard discount rate, adopted by the European Commission and European agencies (e.g., ECHA) in impacts assessments. All monetized values have been adjusted to a base year, assumed to be 2024. Information and data have been aggregated and anonymized. Statements and estimations from the participating companies are as close to real data or perception of future changes as possible.

## 2.2 Overview of industrial test and measurement instruments and their value chain

### General overview

Industrial test and measurement instruments (category 9 – Industrial under the RoHS Directive) are very different from low mix, high-volume consumer products which are frequently re-designed to follow consumer trends and are placed on the market for a limited duration. Industrial test and measurement are high mix, low volume producers, managing portfolios of thousands of highly complex instruments. Each instrument is intentionally designed for high reliability and serviceability to support long useful lifespans, and are made available on the market for at least a decade. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years. Redesign is not frequent and happens every seven years on average (as compared to every 1.5 years or less for consumer products). Once test and measurement instruments are placed onto the market, they are typically accompanied with a long-term customer support arrangement to maintain reliability and calibration.

Product portfolios are widely diversified, with T&M Coalition members each having typically 2,000 to 3,000 products currently made available on the market. These are highly complex, sophisticated electronic instruments such as signal generators, power analysers, oscilloscopes, spectrum analysers, digital multi-meters, electron microscopes, chemical and biological analysers, complex chromatography systems and their detectors, each having necessary options and accessories. Each instrument can have a minimum of 2,000 and up to 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of unique components.

<sup>7</sup> [https://echa.europa.eu/documents/10162/0/afa\\_seac\\_surplus-loss\\_seac-52\\_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138](https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138)

<sup>8</sup> [https://echa.europa.eu/documents/10162/13637/ec\\_note\\_suitable\\_alternative\\_in\\_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1](https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1)



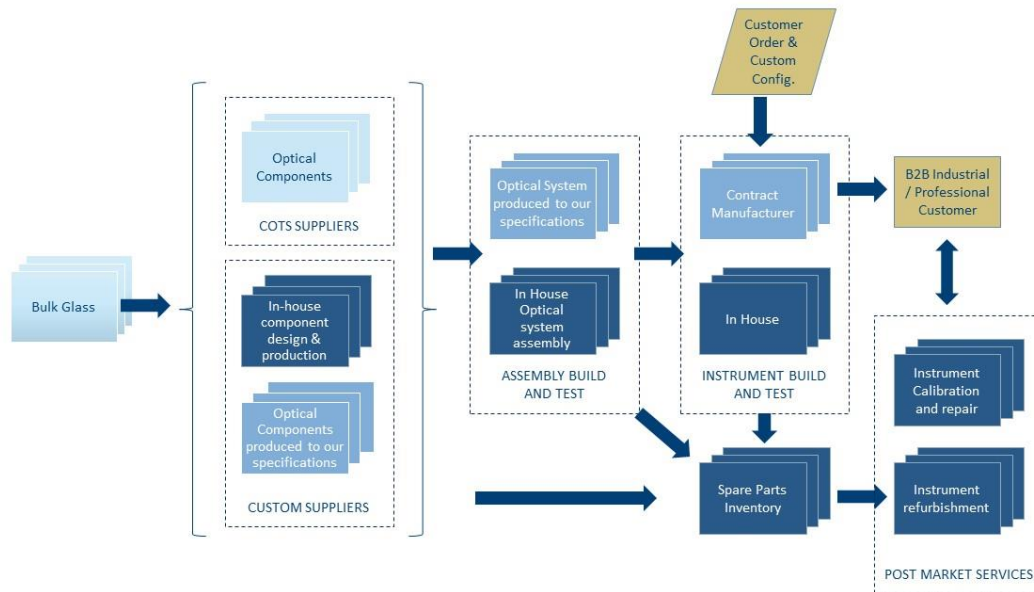
Considering the EU added-value, test and measurement equipment is manufactured and sold in relatively small volumes (per instrument design) and placed on the global market. There is an added value in community level action, which guarantees more coherent and consistent rules across Europe. But with the expansion of RoHS-like requirements beyond the EU, this creates a risk of discrepancies in RoHS-like national laws adopted in third countries.

The professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in Research, Quality Control and Testing laboratories (including field testing) in Universities, Manufacturing and clinical facilities and by Governmental Agencies for conformance verification and environmental testing. They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex and critical systems of all types. The nature of the tests and measurements made by industrial equipment necessitates that the equipment itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components than a typical consumer product.

Historically, between 25 - 35% of the components used in test & measurement products are custom designed. The features of the T&M Coalition's equipment necessitate the development and production of unique components that are not commercially made available on the open market and are typically made by sole, boutique suppliers. These components have their own development lifecycle and take years to bring into production. When these suppliers are unable to deliver compliant parts that meet current RoHS regulations, the product would be stopped from being sold into the EU.

### **Typical supply chain**

The typical supply chain for test and measurement industrial type products is as follows:



- Bulk glass is manufactured globally for component production.
- Optical components are manufactured and sourced globally. These are either produced as commercial off-the-shelf (COTS) products or custom made according to in-house Test & Measurement producers' designs and specifications.
- Optical components are assembled into optical systems in house or produced and tested to Test & Measurement producers' designs and specifications either in-house or by contract manufacturers.
- In response to customer orders or for inventory, finished equipment is configured, built, and tested for global distribution.
- Equipment is supplied into the EU market either directly or through distributors to industrial and professional customers (B2B market).
- Spare parts are made available from the supply chain and utilised in the ongoing support (including servicing, calibration, repair, and refurbishment services) typically provided in-house by Test & Measurement producers.

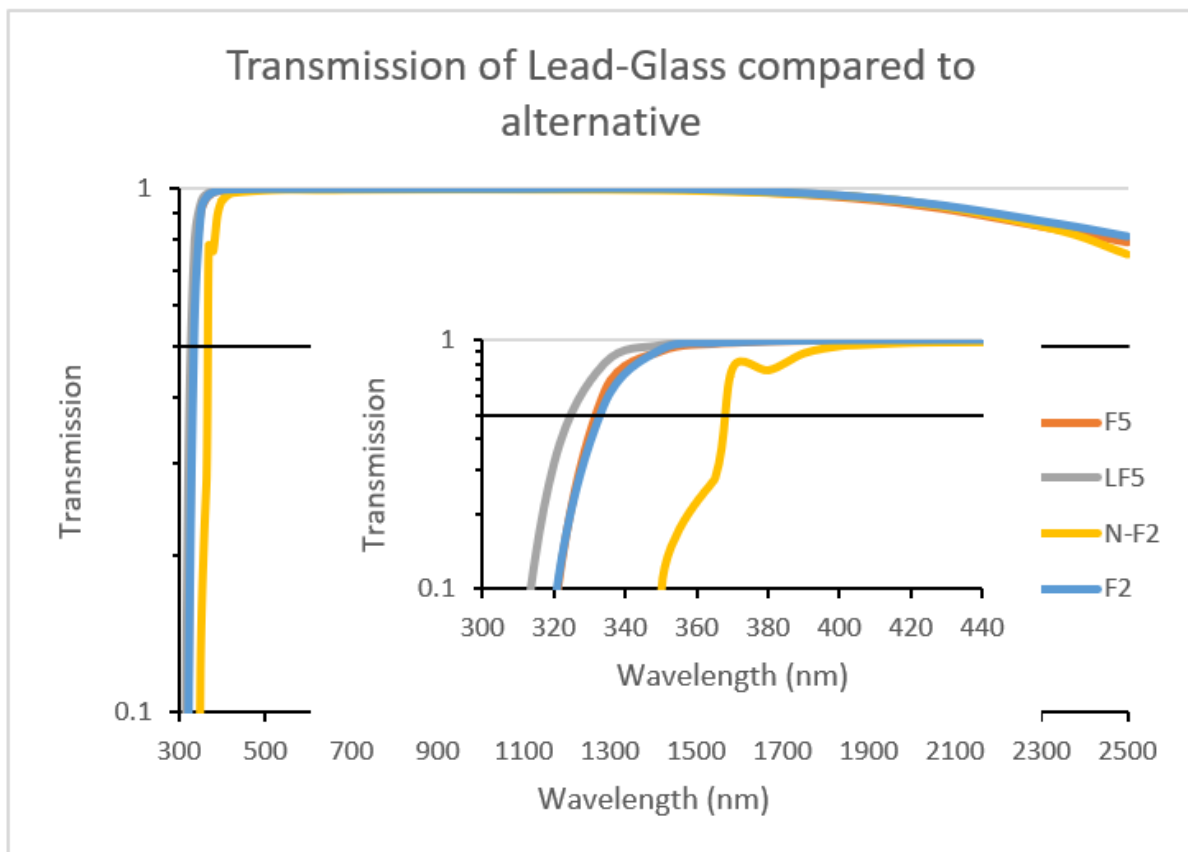
### 3. ANALYSIS OF ALTERNATIVES

#### 3.1 Function and technical performance of Lead (Pb) and Pb-based industrial type 9 products

Exemption 13(a) is an exemption to allow the addition of lead into glass for specific optical components. These optical components (glass lenses, filters, and fibres) are highly specialised, individually specified components that perform a key part of the functionality of the instrument in which they reside. Their use within the heart of the measurement system is such that replacement of these components, even if an equivalent fit, form, and function part is available must undergo rigorous and extensive testing and validation.

## Function of Lead

The addition of lead (typically as PbO) into glass introduces unique properties. As lead is a heavy element, it increases the density of the glass, thereby increasing its refractive index. The typical refractive index of lead glass is  $\sim 1.6$ , compared to 1.46 of typical (soda) glass. In addition to increased refractive index, the addition of lead increases the transmission of light through glass, particularly in the UV spectrum. Figure 1 shows the transmission of various lead glasses (F5, LF5, F2) compared to a substitute glass (N-F2) not containing lead.<sup>9</sup> Although throughout the spectrum the transmission is similar, there is a difference above  $\sim 2400\text{nm}$  in the infra-red, and a substantial difference in the UV below  $370\text{nm}$ .



Optical systems require specific tuning to the application, depending on the signal, optical source, and required measurement accuracy. Test and measurement instruments are typically measuring extremely weak signals. As an example, Raman spectroscopy which is often used for material classification, threat detection, and quality control has an inherently weak signal, typically 0.001% of the source. As such, the optical design for each product is unique, providing stability with the light source (which often subjects the optics to a substantial heat load), such that the measurement can be relied upon. Lead glass is a critical component in these designs. The enhanced refractive index allows for thinner optics, with less chromatic aberration, and the high transmission over a large wavelength range allows for spectroscopic measurements over the full spectrum.

<sup>9</sup> Schott Product data sheets, accessed 13/12/2022.

Fibre optics are utilised for both communications, but also where a detection or imaging cannot be placed close to the signal source. This is common in test and measurement instrumentation, where typically a measurement signal is generated in a complex environment which is not compatible with the sensitive light manipulation and detection process. Transferring the signal can be provided by the use of fibre optics, however, the transmission must be as high as possible in order to optimise the measurement. Where the light signal is of a known particular wavelength, then the specific glass fibre can be selected to have a transmission peak corresponding to the signal wavelength. More commonly, multiple wavelengths are needed, either for colour imaging purposes, or for multiple excitation signals. Such measurements demand fibres with a high transmission curve throughout the optical spectrum. Figure 1 shows the necessity of leaded glass for this application, providing high transmission though UVA (320nm), optical and including the near-infra red (2500nm).

Optical systems and fibre optics are used in a wide variety of test and measurement instrumentation over large application areas. Some of the instrumentation using leaded glass optics and fibre optics include cell imaging systems, multimode UV/visible plate readers, and chromatography systems. This enables spectroscopy and imaging techniques to measure over much broader spectrum. These extreme ends of the spectrum are critical to measurements in the life sciences (Figure 2),<sup>10 11</sup> material analysis<sup>12</sup> chemical analysis.<sup>13</sup>

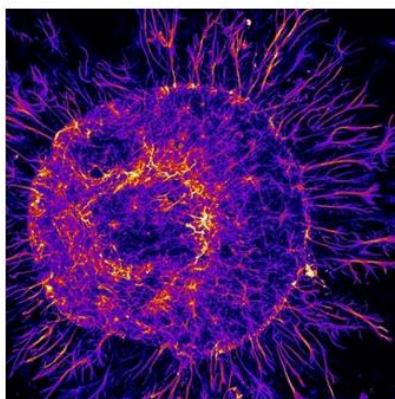


Figure 2: An example of cellular Imaging. A collection of astrocyte cells (glial cells present in brain and spinal cord). Image taken using a cell imaging system based on an optical system containing lead-glass components.

<sup>10</sup> How imaging techniques are innovating drug discovery, Lu Rahman, *Drug Discovery World*, 20 May 2021.

<sup>11</sup> An automated, single cell quantitative imaging microscopy approach to assess micronucleus formation to assess genotoxicity and chromosome instability, Chloe C Lepage et al. *Cells*, 9(2), p. 344 (2020).

<sup>12</sup> High-Performance Liquid Chromatography (HPLC): A Review, A. Hussien Ali, *Annals of Advances in Chemistry* 6, 010-020, (2022)

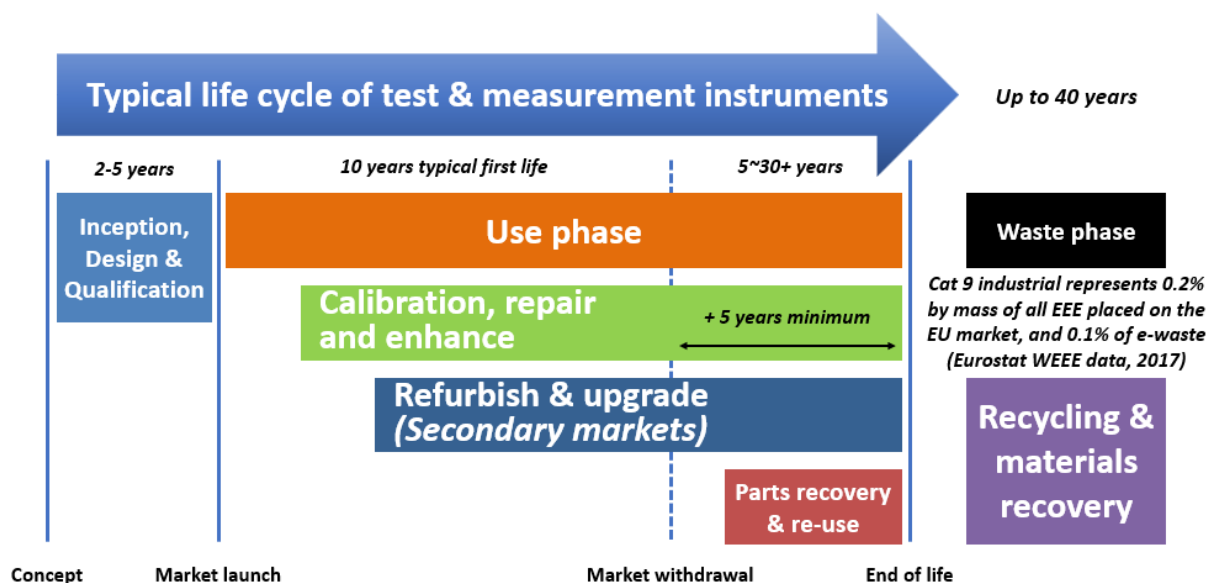
<sup>13</sup> Size-exclusion chromatography as a useful tool for the assessment of polymer quality and determination of macromolecular properties, D. Helt and P. Kilz, *Chemistry Teacher International*, 3(2), pp 77, (2021)



Figure 3: Example of a chromatography system. This instrument is for the analysis and separation of molecules within a liquid by size, and is typically used to separate proteins and other water soluble polymers. Such device is highly complex with over 7000 parts. This spectroscopy system contains optical fibres containing lead-glass.

### 3.2 Typical Industrial Test and Measurement End-to-End Life Cycle

The market sectors addressed by industrial test and measurement equipment can in some cases require that the instruments can be maintained in use for decades. The end-to-end lifecycle model below helps to illustrate how the members contribute to the circular economy by assuring the materials they consume to produce the equipment are kept in use for as long as possible.



The nature of industrial test and measurement instrument applications demand highly accurate and reproducible results throughout their life. With a typical first use of 10 years and a total life of up to 40 years, great care is taken during the design and qualification phases to ensure that the stringent performance and reliability requirements are met and must incorporate design for serviceability. This provides a continuous supply chain of equipment for refurbishment with extended life through resale providing great economic and environmental benefit. Whilst the instruments are designed for long-term reliability, failures do occur during such an extended period of use requiring ability to service and replace parts. After market withdrawal, equipment is normally supported for a minimum of five years. Moreover, refurbishing and reselling on the secondary market are crucial in this sector and often account for 4–5% of producer turnover for test and measurement manufacturers.

Due to the cost, reliability, and unique applications of T&M equipment, many customers do not dispose of the equipment, but instead keep it for use at a later date or place it on the secondary market. Therefore, Category 9 Industrial equipment's contribution to the Waste Electrical and Electronic Equipment stream is very small (0.2% by weight of EU WEEE) with industrial WEEE being collected through B2B systems. Consequently, the environmental impact of industrial test and measurement products is negligible. Nevertheless, test and measurement equipment does enter the waste stream, typically many decades after it is placed on the EU market.

### 3.3 Assessment of potential alternatives to lead (Pb)

To the best knowledge of the Test & Measurement Coalition, there is no substitute available that would be suitable for lead-glass in high accuracy measurement instruments. There are many available alternative glasses that do not contain lead, and low-grade consumer optics are now commonly manufactured from plastics. As shown in Figure 1, the alternatives do not match the optical properties of lead-glass, and even throughout the visible spectrum many of these alternatives have a decrease in transmission leading to losses in the signal. As spectroscopy and imaging plays a greater role in the scientific industries from chemistry to drug discovery and environmental monitoring, it is essential that the industries are able to use the most sensitive and accurate instrumentation.

Since the introduction of RoHS 1, and the restriction of the use of lead, there has been a dramatic improvement in the availability of lead-free glass, and where appropriate these glasses are used. This investment in new glass types continues, and as lead-free glasses approach the performance characteristics of leaded glass then the use of lead glass will naturally diminish. We anticipate that, with continued technical advances, the use of lead glass may reduce to negligible levels within the next two decades. However, at this point, eliminating the use of leaded-glass is not possible without the reduction of performance of critical instrumentation.

#### 3.3.1 Challenges with substitution with alternatives

As stated in the previous section, the companies have indicated that there are currently no suitable alternatives that meet the performance expectations of their customers.

The optical components that utilise lead-glass, as outlined above, perform part of sensitive measurement systems. The optical design is often the first part of the instrument to be designed, as

this defines the parameters of the device. Once the optical design has been finalised, the instrument is then designed around this. Therefore, changing any part of layout of the optical system is typically considered a major redesign, and can be as challenging as designing from scratch. Industrial instrumentation is designed to continuously function reliably and accurately. For the optical systems, not only do the measurements have to be accurate, but they must be stable over time, and not be affected by the heat load of the source, or any other environmental parameters. As such, validation and testing require extended performance assessment to determine the reliance of the system for the expected usage throughout the lifetime of the device.

Members of the Test & Measurement Coalition have pointed out that they principally rely on their suppliers to find alternatives since most of the exemptions used in their products are not produced by the companies but bought off-the-shelf from suppliers (and so forth, potentially many levels down). Implementation of change necessitated by regulatory pressures typically starts with raw material manufacturers and the end-product manufacturers (e.g., Test and Measurement suppliers) who have the largest economic stake. Intermediate manufacturers are geographically and jurisdictionally diverse and are often SMEs. As such, this part of the supply chain is slower and more inconsistently able to adapt. Assuring full adaption in the supply chain and validating the alternatives in the final product application can and often does require up to 4 years. The general process involves communicating with the supply chain, evaluating samples, conducting design impact studies, reconfiguring the instrument and its software where necessary and testing in manufacture and validating the final assembly.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, an additional validation period would be required for each redesigned product that used to utilize the component that relied on the exemption. Moreover, the validation would lead to the organizations incurring additional expenses. These include labour costs and costs arising from potential product resubmission requirements for testing to various notified bodies to ensure that substitution does not create any electrical and functional safety concerns.

Should new lead-free optical parts become available, the participating companies would need to perform a variety of tasks in order to qualify a new part from suppliers. This would divert resources from other projects. It would also increase the cost to ensure the continued availability of the device due to the additional resources required by optics manufactures and by the T&M members. The validation and testing processes would vary according to part complexity and impact upon the final product design which can be categorized as either be of a medium or high complexity:

- **Medium complexity** optical parts are when a like-for-like replacement can be substituted and when the part performs a relatively simple optical function. Despite these characteristics, the change in the optical parameters will require testing and performance validation. The average time to switch a medium complexity part for production is reported to range from **6 to 12 months**.



- **High complexity** parts are optical components that perform a complex function or are part of an optical subassembly. These parts will be critical to the performance and accuracy of the device and will require extensive characterisation as the first step of the replacement process. The output of the characterisation will likely impact other parts of the instrument (for example, the analysis/interpretation software). Once fully characterised, these high complexity optical parts will require testing and validation for their performance and functionality in the instrument. Depending on the application, updated documentation of the device may require notification to the appropriate competent authorities or regulatory bodies. The average time that it would take to perform a high complexity component change for production is between **2 and 5 years**.

### 3.4 Overall conclusion on suitability and availability of alternatives

Research has already been carried out for all applications and in the cases where lead-free alternatives have been found, they are being used. In virtually all applications of optical glass, a combination of three or more properties contribute to the technical performance of lead-based optical white glasses; it is therefore not possible to pick a single property as a criterion of distinction under RoHS. The renewal of exemption 13(a) should accordingly be granted on the ground that there are no alternatives available for the use of lead in white glasses used for optical applications.

Further research, by the optical glass manufacturers, into alternative designs is uncertain and may never be successful due to the demanding combinations of essential characteristics obtained when using lead in white glass. It is therefore not possible for the test and measurement equipment manufacturers, who use the optical glass to predict how much time this type of R&D will take or whether substitutes can be found for all of the diverse applications. It is very probable that it will never be possible to replace leaded glass in all applications. Lead-based glass manufacturers constantly review the published literature on new glass formulations but, in recent years, no new glass types have been discovered that could replace lead-based optical glass. Unless a new formulation is discovered, it is difficult to see what other steps can be taken by glass manufacturers to replace lead. Equipment manufacturers also regularly review their design to assess whether lead-free glass can be used but, for the reasons discussed above, this has not been possible. This echoes the findings in RoHS Pack 23 published on the 19<sup>th</sup> of December 2022.<sup>14</sup>

Where substitution has been possible, it has largely been carried out. Only the applications for which lead-glass is essential remain on the market for reasons related to technical performance. As optical components are essential for these applications and as no comparable lead-free substitutes are likely to be developed in the foreseeable future and by extension the validity period for this exemption, a renewal of exemption 13(a) should be granted.

<sup>14</sup> Study to assess requests for renewal of 12 exemptions to Annex III of Directive 2011/65/EU. Available at: [https://rohs.biois.eu/RoHS\\_Pack-23\\_Report\\_Final\\_20221220.pdf](https://rohs.biois.eu/RoHS_Pack-23_Report_Final_20221220.pdf)



The argumentation presented by the Test & Measurement Coalition in this renewal application is quintessentially already acknowledged by the Commission's external consultants, who assessed the previously submitted application dossiers of other business and industry stakeholders.<sup>15</sup> The report states that in "light of the lack of sufficient alternatives to allow for substitution elimination of the need for lead in white optical glasses in the full product range, an exemption would be justified in line with the Article 5(1)(a) criteria."<sup>16</sup>

Independent of these findings, the Test & Measurement Coalition has contacted their component suppliers to inquire if since the submission of the renewal request by other stakeholders (e.g., Spectaris) new technological developments have occurred that would allow the substitution of cadmium and lead as used in RoHS exemption 13(a). It was reported back that no alternative substance with the same required characteristics of lead and cadmium for the respective components is known to the manufactures of those components.

## 4. ANALYSIS OF IMPACTS

### 4.1 Human health and environmental impacts

Lead is considered to be a reproductive toxin. Given its hazardous properties, lead is on the REACH candidate list of SVHC. Annex II of the Directive 2011/65/EU (RoHS) specifies the restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials. The maximum concentration value for lead (Pb) tolerated by weight in homogenous materials is 0.1% unless there is an application listed in Annex III or IV available to the product category of EEE.

TMC members emphasized that the quantity of lead utilized in their homogeneous materials varies based on the application. Therefore, companies indicated that the homogeneous materials can contain between 37% and 65% lead by weight, with the annual amount of approximately 0.9 kg of Pb entering the EU market annually through the application for which the exemption is requested.

#### 4.1.1 Reduction in the quantity of lead (Pb) placed on the EEA market

The participating companies have reported that no change in releases to the environment of lead are likely to occur during either equipment production or use phases of the concerned products over the next seven years as a consequence of the revocation of the RoHS exemption. During equipment production, the optical glass stays intact and glass waste is controlled. At glass manufacturers, waste and exposure to lead is considered controlled through good OSH management practices.

<sup>15</sup> Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance restrictions in Electrical and Electronic Equipment. Available at: [https://rohs.exemptions.oeko.info/fileadmin/user\\_upload/reports/20160129b\\_RoHS\\_Exemptions\\_Pack7\\_Final\\_Report.pdf](https://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20160129b_RoHS_Exemptions_Pack7_Final_Report.pdf)

<sup>16</sup> Ibid, p. 45

Under normal conditions of equipment use, the lead content associated with the application of exemption 13(a), Annex III is encapsulated within the equipment enclosure and will neither be touched nor released to the environment.<sup>17</sup> As this equipment is sold B2B for professional/industrial use only, equipment that finally reaches end-of-life will be appropriately processed by professional recyclers who are obligated to have suitable controls to avoid any environmental releases and are notified of the presence of the substance under the producers' obligation to provide a SCIP notification.

As a result of the participating companies' relatively low consumption of parts, in comparison to the product Categories 1-7 and 10, renewing this exemption for Category 9 will have a minimal impact on the environment. As previously indicated, Category 9 Industrial producers are only responsible for 0.2% of annual WEEE production. The number of components relying on this exemption that are specialized for test and measurement applications combined with their collective use provide a strong rationale to keep the specialised components, that rely on this exemption, in production. The manufacturing of specialised components will represent a minute fraction of the total exemption usage referenced in this report. The majority of the bulk glass that utilize this exemption, that constitute Category 9 industrial usage, are common to all product categories. The component manufacturers therefore rely on volume use of the other categories to justify their continued production. Renewing this exemption only for Category 9 for the full 7 years will not extend the production life of these higher volume components beyond the exemption renewal period assigned to Categories 1-7 and 10. It will, however, enable the Test & Measurement coalition members to buy sufficient (relatively small) quantities to update the design and continue to use the relevant components for an extended period. As a result, a renewal of this exemption will have a minimal environmental impact and has a positive socio-economic impact by enabling the continued production of Category 9 products critical to the health and welfare of the EU (and global) society whilst the multi-year redesign process is executed.

#### 4.1.2 Additional waste in case of a non-compliant stock

There are no, or at least minimal, expected additional waste before the end of the regular lifetime (non-compliant stock) reported by the companies. Finished goods inventory is typically minimal as T&M equipment manufacturers' production is based on short-term demand, or even per order. Any non-compliant materials will be consumed through sale into markets where there isn't a similar restriction.

## 4.2 Economic impacts

The sections below provide a general overview of the social and economic impacts, considering business impacts (i.e., at different stages of the value chain), market impacts (i.e., on the product market), substitution costs, and broader macroeconomic consequences resulting from a potential non-renewal of the exemption 13(a), Annex III.

<sup>17</sup> All substance is captured in sealed electrical enclosures and chemically or metallurgically bound in alloys, glasses, or ceramics.

#### 4.2.1 Business impacts on manufacturers

A survey was utilized in the preparation of this report. **Data from the TMC member companies have been received and aggregated.** These companies are among the biggest producers in the EEA test and measurement equipment market. The market share covered by this survey is more than 70% of the whole EEA test and measurement equipment market. The assessment is, therefore, highly representative. This large market share can be used to obtain reliable estimates for the EEA market via extrapolation, as detailed below for the assessment of the economic impacts.

Products manufactured by these companies are typically made available on the market for a period of 10 years from market launch until discontinuance. A further five to seven years of guaranteed support life follows discontinuance to assure availability of spare parts. The lifetime of any given unit can often be extended through regular maintenance and servicing. Under normal conditions of use and availability of spare parts, products can remain in use by customers for more than 25 years, supported by repair and calibration services.

Due to the very specialized nature of the industrial test and measurement equipment, sales volumes are in many orders of magnitude lower than those of consumer products. Industrial test and measurement equipment are not subject to fast-paced changes in market patterns. The specialized nature reflects in the prices. The prices of these products vary greatly, depending on factors such as cost, size, and complexity.

The TMC member companies have declared that more than [CONF.] product lines that apply this exemption would be impacted. During 2021, [CONF.] units of these products were placed on the EEA market. These data were taken from a typical sales year and the volumes are considered representative for annual volumes.

Depending on the part complexity, different compliance costs are also to be expected. The companies emphasized that switching to RoHS compliant products without using the exemption would require a disruptive amount of work and investments. Adapting an alternative optical glass will likely require a nearly complete, redesign of the products in the scope of the exemption. This would need to be done with a finite availability of resources and specialized engineers, a high proportion of custom parts, extensive testing, and re-qualification requirements before products could be marketed. Increased capacity of test facilities would also be required to verify in parallel a larger than normal range of products – many of which are already taxed beyond capabilities to accommodate unrelated changes to the EU IVDR/MDR and created by Brexit.

Given the fact that new products drive long-term company growth, the time spent sustaining existing products directly impacts the company's growth, resulting in a large opportunity cost. Further, significant testing must be done to ensure that alterations will not affect the quality and performance of the final product since T&M equipment is particularly sensitive to component, material, and manufacturing changes. Therefore, **considering the number of products affected by this restriction, the expected amount of investments to comply with the restriction would be more than [CONF.] EUR (rounded).** Additional costs due to loss of efficiencies and additional R&D spending at companies' suppliers are to be expected.

Therefore, the non-renewal of the Annex III, exemption 13(a) exemption would have significant impacts on their business and customers. The companies reported that due to the specificity of the equipment, there are no known methods to produce compliant equipment (cf. Annex I to this report for details on product groups) meeting the specific performance specifications of production today.

As a consequence of these technical and practical challenges, the TMC manufacturers anticipate loss of business in the EEA. The direct cost of a non-renewal of the exemption is represented by the loss of the contribution to the EEA economy of the EBIT generated by manufacturers using lead (Pb) in optical glass. The relevant economic measure to quantify this economic impact is given by EBIT. The monetization (net present value, NPV, with 4% discount rate) of this economic impact (lost EBIT) is reported below.

Therefore, if Annex III, exemption 13(a) would not be renewed,<sup>18</sup> it is estimated that **manufacturers of test and measurement equipment using lead (Pb) in white glasses used for optical applications would face a net EBIT loss of approximately [CONF.] EUR/year. Over four years**, the total impact is expected to be approximately **[CONF.] EUR (NPV, 4% d.r.)<sup>19</sup> for the manufacturers.**

We can use the market share of the test and measurement equipment manufactured by the participating companies to extrapolate **the total economic impact in the EEA across all manufacturers.** The market share covered by this survey represents more than 70 % of the whole EEA test and measurement equipment market. This market share is used for the extrapolation of the impacts for the whole EEA market in a conservative approach. **The total impact for the EEA market (manufacturers of test and measurement equipment) would therefore be in the range of [CONF.] EUR (derived above) and [CONF.] EUR ([CONF.] EUR x 1/0.70).**

Other companies may benefit from a negative regulatory outcome for lead, especially, competitors based outside the EEA. Because the RoHS restrictions would affect equally the whole EEA T&M industry, the corresponding loss in value added (i.e., loss in EBIT) can be considered an EEA industry-wide impact.

It must be noted that what occurs in Europe also has repercussions on other markets, such as the Asian market. This is because the CE mark is used by T&M equipment manufacturer as evidence that their products are suitable for the EU and therefore are considered of acceptable quality in a non-EEA location. Consequently, the economic consequences of a non-renewal for Annex III, exemption 13(a) would result in much larger impacts for the industry than those reported above.

<sup>18</sup> Companies were asked to consider how the revenues (and EBIT) for year 2022 were impacted under the assumption that a RoHS restriction on lead in test and measurement industrial products types were to be fully adopted with immediate effect (i.e., in 2023).

<sup>19</sup> Using the Excel function =PV(4%,4,-[CONF],0,0).

Given the specificity and complexity of industrial test and measurement instruments, it is extremely challenging for the test and measurement sector to adapt to frequent changes of the lead restriction in scope. The main challenge that has been raised by the companies is the fact that deadlines provided by authorities are considered too tight for business adaptability and to develop alternative products. The existing maximum renewal duration of up to 7 years is considerably shorter than product development lifecycles. This renewal request is therefore made to cover the full seven-year maximum duration.

### **Substitution costs for test and measurement equipment manufacturers**

All of the bulk glass utilizing exemption 13(a) incorporated into T&M equipment are COTS parts. T&M manufacturers are entirely reliant to their suppliers to identify alternatives.

It is estimated that 2 years are needed to evaluate the suitability of potential alternatives and that additional 3-5 years are needed for implementing the substitution or concentration reduction of RoHS restricted substances, depending on the complexity of the product, if a substitution candidate could be identified.

As the companies do not manufacture the optical glass parts incorporated into test and measurement equipment and purchase the most parts from the respective suppliers, **implementing a re-design require longer timelines to convert the entire portfolio and will incur significant cost increases.** The change would involve researching an alternate material, assembling it into a test product, and evaluating the new product for functionality, hardware and software performance, reliability, EMC, safety, manufacturability etc.

Therefore, **the T&M Coalition member companies have indicated that the implementation of substitution or concentration reduction of lead would cost approximately [CONF.] EUR (rounded),<sup>20</sup>** including validation and testing, engineering, quality and administrative costs. This also includes incremental investment necessary to characterize potential substitutes, and where practicable, tailor production processes to assure existing product's published specifications can be maintained. These additional costs will be partly transferred to customers over the next few years after the potential non-renewal, mainly due to the use of specialty components.

In reality, the switching costs are likely to be much larger than the estimate above. By making use of the market share of about 70% covered in this SEA, we can extrapolate a **total switching cost of [CONF.] EUR (= [CONF.] EUR \* 1/70%)** for all manufacturers of test and measurement equipment industrial products.

## **4.3 Wider economic impacts**

<sup>20</sup> ECB exchange rate on 11 October 2022 (1 EUR = 0.9723). Available at: [https://www.ecb.europa.eu/stats/policy\\_and\\_exchange\\_rates/euro\\_reference\\_exchange\\_rates/html/eurofxref-graph-usd.en.html](https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-usd.en.html).

It is also important to consider the wider macroeconomic impacts and consequences on the EU society at large, by focusing on the expected consequences for the EEA market. In particular, there are concerns on the overall EU trade balance (increase of imported test and measurement industrial product types) and on the competitiveness of EEA market.

### **Impacts on the market – Quality and costs**

If **Annex III, exemption 13(a)** would no longer be available for use in test and measurement equipment, sectors relying on these products would be particularly affected. Many sectors utilize the equipment; a non-renewal will, however, particularly have a negative impact on lithography (used in the production of integrated circuits), precision position measurement solutions, the life science, chemical, clinical and environmental monitoring industries, where equipment utilizing 13(a) exemption is used extensively.

For the majority of products that utilize Annex III, exemption 13(a) it is not possible to remove the exempt components without risk to product safety, quality, reliability or performance. For products where lead-free glass optical components become available, conversion to become exemption-free would be prioritized by EEA revenue as it likely would not be worth the investment to re-design all products to be exemption-free. Even if there were suitable alternatives on the market today, it is expected to take several years or more to convert the entire companies' portfolio. This would likely result in a withdrawal of products from the market until products are converted. Any low revenue products that require significant re-design, or products that are within a few years of obsolescence, are likely to be withdrawn from the EEA market.

The impact of reduced volumes manufactured will also have a **significant impact on the fixed costs of various supply chain actors**. Participating companies would also be strained by increased costs associated with addressing new product development and resourcing components for manufacturing. As a result, prices of final products would increase accordingly.

### **Impacts on suppliers**

The participating companies maintain a large supply chain: a vast amount of actors supply components, materials, and performs contract manufacturing operations. This supply chain is global and not limited to businesses located in the EEA. There are a number of actors in the production of the impacted equipment produced by the applicant: component and sub assembly suppliers, contract manufacturers for specific optical assemblies, and contract manufacturers for selected products' assembly. Most of these suppliers leverage RoHS exemptions in their supply chain.

If **Annex III, exemption 13(a)** would not be renewed, **there would be a decrease in demand for the services of each actor in the supply chain**. These suppliers are at a risk of losing these sales and the need to develop new technologies to replace their existing products. Depending on the speed of R&D, they could permanently lose sales if a competitor brings a replacement to market faster.

The greatest direct impact would be on the bulk glass materials, component and subassembly contract manufacturers whose core business is to provide such items to the electronics market. Reduced product volumes from equipment producers would also affect profitability (reduced volumes vs. fixed costs) of contract manufacturers. **The supply chains of the participating companies would require a lengthy transition period in case of non-renewal** as they would need to resource alternative materials, validate the production of optical components with new materials, and build the critical sub-components that are used to assemble and manufacture equipment on behalf of the TMC manufacturers.

#### **Impacts on the market – Competitiveness**

As the RoHS regulation applies to all producers equally when placing equipment on the EEA market and since the majority of the production is based outside of the EEA (mainly in the US), **a non-renewal of the Annex III, exemption 13(a) for test and measurement industrial product types in the EEA would disadvantage the EEA markets in their competition with the rest of the world.**

Indeed, as other regions have RoHS-equal regulations which are not market restricting but rather mainly notification based, if the exemption 13(a), Annex III is removed, the risk is that test and measurement equipment manufacturers will be forced to look at other growth areas, such as, for example, the Asia-Pacific region. T&M equipment manufacturers' supply chain is global and not limited to businesses located in the EEA. Their portfolio is highly specialized and so equipment is built for global distribution. Therefore, manufacturers cannot afford to regionalise the production. **The manufacturing of a specific variant of a product for distribution only within the EEA is not an economically viable option.** This would negatively impact the competitiveness of EEA market players compared to those that have access to a wider portfolio of test and measurement instruments in other areas of the world.

Furthermore, non-EEA competitors would not be subject to restriction and would be able to supply and place on the international market a wider range of products, without bearing any redesign costs. Thus, non-EEA competitors are likely to gain market share if the restrictions are applied in the EEA market. In particular, the Asia-Pacific region could greatly benefit in terms of possibility of increasing their market share by taking advantage of the opportunity of additional production. **The gap in availability of products to the EEA will impact the ability of many actors to perform the necessary functions to compete with non-EEA markets.**

#### **Impacts on the market – Innovation and R&D**



**The revocation of Annex III, exemption 8(b) is expected to have wider impacts on innovation in Europe.** One of the major uses of the Category 9 products is in essential research and development processes, both within private companies and for state sponsored research. The limited access to test and measurement equipment in the EEA will constrict investment in both innovation and commercialization of new technologies in a wide variety of sectors, from life science to chemical and from engineering to material science and chip production. The limited access to test and measurement equipment in the EEA will be the main driver for investment in both the development and production of all electronic equipment to other non-EEA regions. This will have a market impact on the innovation and the know-how in the EEA. The removal of products from the market due to the non-renewal of exemption 13(a), will therefore have a **direct negative impact on the research and innovation output within the EEA.**

A possible non-renewal will, as noted before, influence the EEA market's competitiveness and significantly affect the sales of the companies. The significant reduction in sales as a result of a possible non-renewal of **Annex III, exemption 13(a)** will have an inevitable negative impact on R&D investments. Therefore, based on the assumption that the percentage of revenue spent remains the same, the loss of sales to the EEA market will result in a decrease in R&D spending. Moreover, the manufacturers have further noted that the current geopolitical situation, supply chain disruptions and the inflated cost of materials has already resulted in a cut in R&D investments. The non-renewal of the exemption would solely exacerbate the lack of and decrease in R&D funding.

The current R&D efforts and resource would inevitably be redirected towards redesigning legacy products to accommodate alternate materials and will only exacerbate the lack of and decrease in funding R&D for additional T&M equipment products. The non-renewal of Annex III, exemption 13(a) would **adversely affect the resources available for new product design and innovation, as the limited R&D resources available would be spent on responding to a non-renewal instead.**

#### **Impacts on the market – Trade**

When assessing this aspect, it is important to consider the trade balance of the EU. **A non-renewal of Annex III, exemption 13(a) would disadvantage European companies in their trade with the rest of the world.** The exports from the EEA would be particularly hard hit by a potential restriction (non-renewal of the exemption). As a result, the **overall EU trade balance would be adversely impacted.**

#### **4.4 Social impacts: unemployment**

The restriction of lead will not have a direct impact on the headcount of the manufacturer companies. The headcount is dynamically changing based on different factors, including customer relationships, opportunities and market dynamics.

In general, it is difficult to estimate the unemployment because this depends on whether the end user market can be addressed in the future with products that do not rely on Annex III, Exemption 13(a) and if that transition is capable of retaining the same precise product specifications and reliability performance.



However, the TMC manufacturers declared that a non-renewal would very likely lead to unemployment within the companies. With the loss of business, action would be deemed necessary to reduce workforce, especially high-skilled (e.g., scientists, engineers, microbiologists, and quality experts). It is estimated that, assuming a RoHS restriction is implemented, approximately **[CONF.]** highly skilled workers in the companies participating in the survey will face layoff in the EEA.<sup>21</sup> Here we report the monetization of the likely social costs of unemployment for these workers.

For the purpose of this SEA, it is assumed that the average annual salary across these European workers (including the employer's social security contributions) is **[CONF.]** EUR.

A well-known guideline in monetizing the social impact of unemployment has been developed by the European Chemicals Agency (ECHA) for evaluating such impact in different regulatory processes.

Estimates have been made in accordance with the ECHA document on the evaluation of unemployment (SEAC/32/2016/04)<sup>22</sup> and the paper of Dubourg (2016)<sup>23</sup> endorsed by ECHA. Therefore:

- Using Table A7 (column G, considering the gross wages including the employer's social security contributions) in Dubourg's paper, the total social cost of unemployment in EU is equal to 2.16 times the annual gross salary.<sup>24</sup>
- Table 1 presents the statistics from Eurostat (data for 2021-Q3) on the average duration of unemployment for both men and women in the age of 15-64 years in EU-27.<sup>25</sup>
- Only 75% of the average duration of employment is considered, to reflect the fact that some affected workers are highly skilled and could find employment sooner.

**Table 1. Duration of unemployment in EU-27**

Duration Grouping	Thousand units	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	1328.5	0.096128799	0.5	0.048064399
From 1 to 2 months	2585.5	0.187083936	1.5	0.280625904
From 3 to 5 months	2175.0	0.157380608	4.5	0.708212735
From 6 to 11 months	1953.3	0.14133864	8.5	1.201378437
From 12 to 17 months	1637.8	0.118509407	14.5	1.718386397
From 18 to 23 months	640.3	0.046331404	20.5	0.949793777

<sup>21</sup> Due to the lack of sufficient data from several of the participating companies, we adopt the conservative estimate of at least 20 workers being laid off in the EEA for per company.

<sup>22</sup> ECHA (2016). The Social Cost of Unemployment. Available at: [https://echa.europa.eu/documents/10162/13555/seac\\_unemployment\\_evaluation\\_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcb35d25](https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcb35d25)

<sup>23</sup> Richard Dubourg, 2016. Valuing the Social Costs of Job Losses in Applications for Authorization. The Economics Interface Limited.

<sup>24</sup> This value is greater than one (1) because it takes into account the following components: lost wage, costs of job searching, recruitment costs, the impact of unemployment status on future wages (scarring effect) and employment possibilities, and leisure time (which is a benefit and therefore subtracted from the previous components).

<sup>25</sup> Data extracted from [http://appsso.eurostat.ec.europa.eu/nui/show.do?wai=true&dataset=lfsq\\_ugad](http://appsso.eurostat.ec.europa.eu/nui/show.do?wai=true&dataset=lfsq_ugad)

From 24 to 47 months	1651.0	0.119464544	35.5	4.240991317
48 months or over	1848.6	0.133762663	48	6.420607815
Total	13820.0	1		<b>15.56806078</b>

The social costs of unemployment would therefore be equal to:

**[CONF.]** EUR x **[CONF.]** people x 2.16 x 15.56806078/12 x 75% = **[CONF.]** EUR.

Although companies along the supply chain would face a reduction in sales over the years, we assume for simplicity that the entire workforce will continue working for other three years. Therefore, we discount the monetized impact derived above by three years due to the assumed delay in the layoff, using discount rate of 4% per year, as follows: **[CONF.]** EUR x  $(1 + 0.04)^{-3}$  = **[CONF.]** EUR.

As reported above, the test and measurement industrial type products' manufacturers (participating in the survey) use in total 0.9 kg of lead per year related to the application of Annex III, exemption 13(a). One can use the tonnage (proxy for market share) of test and measurement industrial products to extrapolate the total social impact of the unemployment in the EU across all T&M manufacturers: **[CONF.]** EUR x 1/0.70 = **[CONF.]** EUR (rounded).

Other (low-skilled) workers would be impacted, even though the TMC manufacturers are not in a position today to quantify the unemployment effect.

Moreover, as a progressive result and due to the expected reduction in sales, job creation is also expected to be negatively affected. Manufacturers anticipated that eventually they would inevitably reduce new recruitment.

**We can affirm with a high likelihood that the total social impact of a restriction of lead used in white glasses used for optical applications *along the whole supply chain* would be much larger than **[CONF.]** EUR, once one considers all other economic operators having business linked to test and measurement industrial equipment products.**

## 5. CONCLUSION

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This SEA identifies the main potential negative consequences that the EU society at large would face in the framework of the potential restriction of lead in white glasses used for optical applications. It has been performed in line with existing ECHA guidance for the preparation of the Socio-Economic Analysis. The results are based on a survey focused on the EU test and measurement equipment industry, with market share coverage of approximately 70% of the EU market. It therefore provided sufficiently reliable data for a representative extrapolation of the EU market.

**Overall, the results of the SEA demonstrate the safe use of lead (Pb) in white glasses used for optical applications and can reasonably justify the renewal of this exemption on the grounds that a broad restriction would have disproportionate negative impacts on society when compared with the risk to human health, animal health or the environment.**

The **total monetized impact** of a non-renewal is estimated in the range of **1.2 billion EUR and 1.6 billion EUR**, including: **[CONF.]** EUR of economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; **[CONF.]** EUR of substitution costs; **[CONF.]** EUR of social impacts deriving from unemployment. This is a conservative estimate (lower bound), on the understanding this is not the sole injury likely to be suffered in the EU.

In terms of **business and market impacts**, a non-renewal would constraint most of the companies currently supplying RoHS-based test and measurement industrial products to cease production and business activities of all products that include lead.

In addition, and pursuant to Article 5 of the RoHS Directive a continuation of exemption 13(a) Annex III is warranted as **no suitable alternatives to the RoHS restricted substance are available**.

## ANNEX I

### Product groupings and equipment types relevant to exemption 13(a)

Product Grouping	Equipment Types
Generators, Sources and Power	Waveform and Function Generators
Application-Specific Test Systems and Components	
Photonic Test & Measurement Products	
Laser Interferometers and Calibration Systems	Monolithic Laser Combiners & Precision Optics
Used Equipment	
Liquid Chromatography	
Gas Chromatography	
Cell Analysis	
Laboratory Products and Industrial Monitoring Capital Equipment	Autoclave Sterilizers
	Baths and Circulators
	Biological Safety Cabinets
	Blood Culturing Devices
	Centrifuges
	Chillers
	Electrophoresis
	Environmental Chambers
	Freeze Dryers
	Furnaces
	Heat Controllers/Exchangers
	Ovens
	Refrigerators
	Freezers
Material and Structural Analysis	Mixers
	Water Purification
	Electron Microscopes
	Spectroscopy Equipment



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