

Exemption Request Form

Date of submission: 20 January 2023

1. Name and contact details

1) Name and contact details of applicant:

Company: Test & Measurement Coalition Tel.: +32 2 735 82 30
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Function: TMC Secretariat Address: Place du Luxembourg 2, 1050
Brussels, Belgium

2) Name and contact details of responsible person for this application (if different from above):

Company: _____ Tel.: _____
Name: _____ E-Mail: _____
Function: _____ Address: _____

2. Reason for application:

Please indicate where relevant:

- Request for new exemption in:
 Request for amendment of existing exemption in
 Request for extension of existing exemption in
 Request for deletion of existing exemption in:
 Provision of information referring to an existing specific exemption in:
 Annex III Annex IV

No. of exemption in Annex III or IV where applicable: 7(c)-I

Proposed or existing wording: Existing

“Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound.”

Duration where applicable: Maximum validity period

Other: _____

3. Summary of the exemption request / revocation request

Exemption 7(c)-I is the most frequently used exemption in T&M electronic products: most electronic products contain this exemption because of the broad range of applications.

As further outlined in this submission there is no single substitute available that would be suitable to all the applications identified. The Test & Measurement Coalition therefore applies for a renewal of exemption 7(c)-I for the maximum validity period.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 7(c)-I would have at this stage. Overall, the analysis concludes that the total impact of non-renewal of this exemption is monetized in the range of 3.1 billion EUR and 4.3 billion EUR (conservative lower bound estimate).

4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products:

Industrial test and measurement instruments (category 9 – industrial under 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 instruments are high mix, low volume producers, managing portfolios of thousands of highly complex. 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 many necessary options and accessories. The Annex of this SEA contains further details concerning the product groupings and equipment types of the participating companies. Each instrument can have between 2,000 and 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of items.

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. 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.

Please refer to the table below for a comprehensive list of the relevant product groupings and equipment types relevant to exemption 7(c)-I.

Product Grouping	Equipment Types
Oscilloscopes, Analyzers & Meters	Oscilloscopes
	Spectrum Analyzers (Signal Analyzers)

Product Grouping	Equipment Types
	Network Analyzers Logic Analyzers Protocol Analyzers and Exercisers Bit Error Ratio Testers Noise Figure Analyzers and Noise Sources High-Speed Digitizers and Multichannel DAQ Solutions AC Power Analyzers DC Power Analyzers Materials Test Equipment Device Current Waveform Analyzers Parameter and Device Analyzers, Curve Tracers (Digital) Multimeters Phase Noise Measurement Power Meters and Power Sensors Counters LCR Meters and Impedance Measurement Products Picoammeters & Electrometers Oscilloscope Upgrades and Accessories
Generators, Sources and Power	Signal Generators (Signal Sources) Waveform and Function Generators Arbitrary Waveform Generators Pulse Generator Products HEV/EV/Grid Emulators and Test Systems DC Power Supplies Source Measure Units DC Electronic Load AC Power Sources Sourcemeter Sensitive Meter/Source
Wireless	Wireless Network Emulators Channel Emulation Solutions Nemo Wireless Network Solutions 5G OTA Chambers Wireless Analyzers IoT Regulatory Compliance Solutions
Modular Instruments	PXI Products AXIe Products Data Acquisition – DAQ USB Products VXI Products Reference Solutions
Network Test, Security & Network Visibility	Protocol and Load Test Network Test Hardware Cloud Test Performance Monitoring 5G NR Base Station Test Radio Access and Core Network Test Network Security Cyber Training Simulator Network Modeling Application and Threat Intelligence Network Packet Brokers Cloud Visibility Network Taps Bypass Switches Clock Synchronization
Application-Specific Test Systems and Components	

Product Grouping	Equipment Types
Photonic Test & Measurement Products	
Laser Interferometers and Calibration Systems	Monolithic Laser Combiners & Precision Optics
In-Circuit Test Systems	
Used Equipment	
Bioprocessing Equipment Automation	Large Chambers Mixers for Processing Drug Intermediaries
Laboratory Products	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 Mixers Water Purification
Chemical Analysis	Handheld XRF Analyzers Dosimetry Personnel Contamination Monitors (Laser) Spectroscopy
Genetic Sciences	Gold Standard Products for COVID-19 PCR Testing Modules
Other	Test and Measurement Upgrades and Accessories Probe Semiconductor Characterization System Chromatography Mass Spectrometry Gas Chromatography Smart Docking Solutions Electron Microscopes Series Controllers Value Controllers Distributed Nodes Embedded Networks Hardware Ethernet Hardware Industrial Communications Hardware Industrial Controllers Motion Control Hardware Multifunction Instruments Programmable Power Supplies Embedded Controllers Remote Controllers Astronomical Equipment

a. List of relevant categories: (mark more than one where applicable)

- | | |
|----------------------------|---------------------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 7 |
| <input type="checkbox"/> 2 | <input type="checkbox"/> 8 |
| <input type="checkbox"/> 3 | <input checked="" type="checkbox"/> 9 |
| <input type="checkbox"/> 4 | <input type="checkbox"/> 10 |
| <input type="checkbox"/> 5 | <input type="checkbox"/> 11 |
| <input type="checkbox"/> 6 | |

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

monitoring and control instruments in industry

in-vitro diagnostics

other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

(Indicate more than one where applicable)

Pb Cd Hg Cr-VI PBB PBDE

3. Function of the substance:

For T&M instruments, lead-containing glass as part of thick film inks or encapsulating materials is used on ceramic substrates or organic substrates.

Glass frit particles in thick film inks are used for electronic circuitry. The glass portion is comprised of vitrified oxides forming a glass matrix. The functions of the glass include, for instance, a barrier to prevent the migration of silver; a sealing material for hermetic ceramic and metal component packages (semiconductors and hybrids); and control of the coefficient of thermal expansion used in high temperature sintering operations.

However, it should be noted that there are varied and eclectic uses for lead in glass and ceramics for electronics applications and therefore cannot be enumerated in its totality. This is a fact that has also been pointed out by other industry associations in their submissions for a renewal request of exemption 7(c)-I (see for instance application of the RoHS Umbrella Industry from January 2020).¹

¹ Previous applications for RoHS exemptions or their renewals are publicly available and downloadable from the Commission webpages. Available at: https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

4. Content of substance in homogeneous material (%weight): 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 3% and 93% lead by weight.
5. Amount of substance entering the EU market annually through application for which the exemption is requested: Approximately 8.2 kg of Pb.
Please supply information and calculations to support stated figure.
The amount of substance entering the EU market annually through application for which the exemption is requested is based on the replies provided by the TMC members (for the preparation of the Socio-Economic Analysis – see attached).
6. Name of material/component: Printed circuit boards, printed circuit assemblies.
7. Environmental Assessment: _____
LCA: Yes
 No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Exemption 7(c)-I is the most frequently used exemption in T&M electronic products; most electronic products contain this exemption because of the broad range of applications. These include, but are not limited to, the following:

- Resistor networks
- Diodes
- DC-DC converters
- Microwave and mmWave frequency custom components
- Thermistors
- Thyristors
- Relays
- Crystal oscillators
- Bandpass filters
- Amplifiers
- Couplers
- High frequency RF filters

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The use of lead in glass and ceramic materials provides superior properties and reliability compared to lead-free alternatives. The specific advantages are:

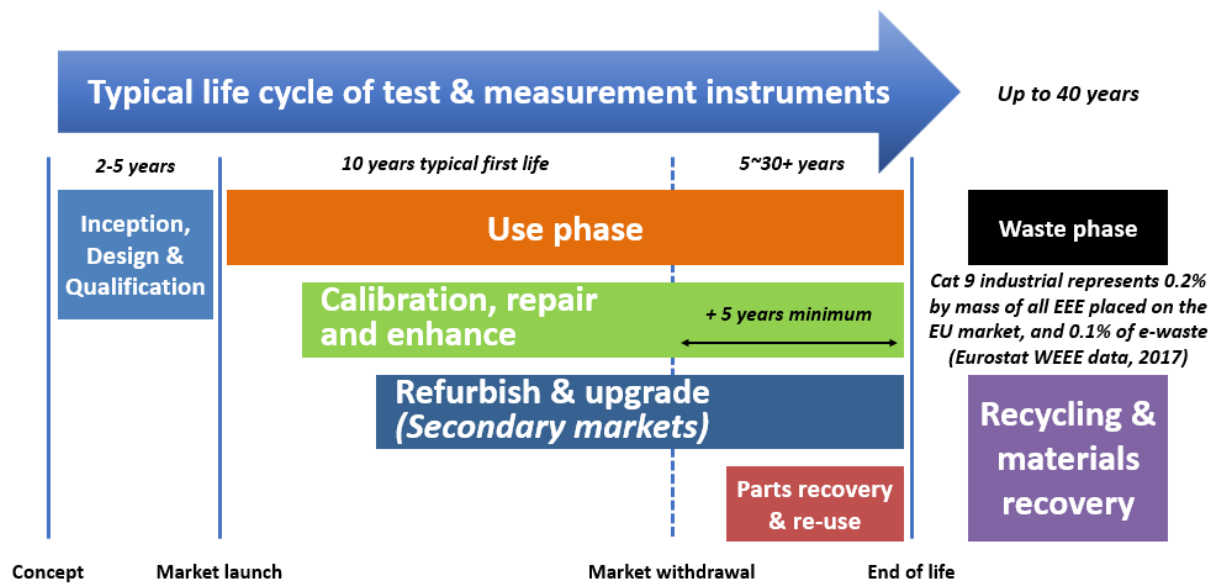
- Lower melting point, allowing usage with a broader range of materials.
- Better control for coefficient of thermal expansion, which reduces stresses and resultant cracking.
- Better wetting, allowing penetration into tighter spaces and effective sealing.
- Less reactivity to environment, resulting in longer life in humidity, temperature extremes and electrical loads.
- Less degradation of the material over time, resulting in greater precision and stability in resistive values.

5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

- 1) **Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)**

There is no specific closed loop system in place. Please find below some specific considerations on the typical End-to-Life Cycle of category 9 industrial Test and Measurement instruments:

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.

2) Please indicate where relevant:

- Article is collected and sent without dismantling for recycling
- Article is collected and completely refurbished for reuse
- Article is collected and dismantled:
 - The following parts are refurbished for use as spare parts: PCAs, microcircuits
 - The following parts are subsequently recycled: cables, metal
- Article cannot be recycled and is therefore:
 - Sent for energy return
 - Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

No detailed data available.

- In articles which are refurbished _____
- In articles which are recycled _____
- In articles which are sent for energy return _____
- In articles which are landfilled _____

6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

To the best knowledge of the Test & Measurement Coalition, there remains no single substitute available that would be suitable to all the applications identified. Currently, substitutes for even the major uses have rarely been found. Evaluating alternatives for each of the niche uses would take an enormous amount of time and resources, with little probability of success.

The overall lack of a suitable alternative for lead as used in exemption 7(c)-I has also been echoed in the application submissions of other businesses relying on this particular RoHS exemption. Industry as a whole has been involved in finding substitutes for lead in glass, ceramic, or glass or ceramic matrix compounds for more than two decades.² Despite these tremendous efforts, a substitute for lead that is broadly applicable to the numerous applications has not been found.

² A comprehensive overview of industry's efforts in this regard is outlined in the exemption renewal dossier of the Umbrella Project, which is downloadable from the Commission's webpage. Available at: https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

For instance, low melting point (LMP) glass solders have been attempted with multiple substances with no success: They either melt at too high of a temperature (120-160°C higher); do not perform functionally (do not wet, do not seal); or are more toxic than Pb (such as beryllium oxide BeO, uranium dioxide UO₂) – or a combination of these.³

Additionally, lead-free resistor element materials have poorer reliability than Pb-containing materials due to low moisture resistance during load heating and low mechanical strength during overload heating. Resistance values are not stable, changing gradually over time or sometimes with sharp changes.⁴ For the accuracy and long life required by T&M products, substitutes with these technical inadequacies are not acceptable.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

Please refer to point A.

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Taking into consideration the unique characteristics of lead, no suitable alternative to lead for RoHS exemption 7(c)-I could be identified.

The argumentation presented by the Test & Measurement Coalition in this renewal application is quintessentially already acknowledged by the Commission's external consultant Öko-Institut, which finalised its assessment of the previously submitted application dossiers of other business and industry stakeholders for the renewal of RoHS exemption 7(c)-I in 2022.⁵

³ Ibid

⁴ Ibid

⁵ European Commission/Öko-Institut e.V., (2022), "RoHS Exemptions Evaluation: Pack 22 – Study to assess requests for a renewal of nine (-9-) exemptions 6(a), 6(a)-I, 6(b), 6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I and 7 (c)-II of Annex III of Directive 2011/65/EU (Pack 22) – Final Report (Amended Version)." Available at: https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_22/RoHS_Pack-22_final_report_amended_February_2022.pdf

In their pack 22 assessment report Öko-Institut concludes based on the input provided by the dossier submitters that the “*exemption is justified as available substitutes are either not suitable and cannot be fabricated into lead-free components that could be used in the same applications, or such components provide an inferior reliability leading to malfunctions that would not be acceptable in the respective EEE*”.⁶

Independent of these findings, the Test & Measurement Coalition has contacted their component suppliers to inquire if, since the submission of the renewal request in 2020 by other stakeholders (e.g., the Umbrella Project), new technological developments have occurred that would allow the substitution of lead as used in RoHS exemption 7(c)-I. It was reported back that no alternative substance with the same required characteristics of lead for the respective components is known to the manufactures of those components.

Based on these facts the companies of the Test & Measurement Coalition believe that a renewal of RoHS exemption 7(c)-I in accordance with Article 5(1)(a) of the RoHS Directive is warranted.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

Members of the Test & Measurement Coalition have pointed out that they principally rely on their component suppliers to find alternatives to the use of restricted substances since most of the components utilizing exemption 7(c)-I incorporated into T&M equipment are COTS parts (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.

⁶ Ibid, p. 178

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, a 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.

If a new substance free part is available, this part must be qualified for use by performing a variety of tasks, as described above. Due to the complexity and diversity of the applications, this must be done individually by each company for each product group. This process would divert resources from other projects and increase the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity and impact upon the final product design; which can be categorised as low, medium, and high:

- **Low complexity** parts are the off-the-shelf components or hardware parts that do not have a substantial performance impact. Replacement can be done based on supplier information, assuming a form/fit/function compliance, with standard manufacturing, testing, and validation processes. Based on process timescales reported by a T&M coalition company, the average time that it can take for these parts to be replaced ranges from **3 to 6 months**.
- **Medium complexity** parts are more complex sub-assembly electronic parts, such as small motors, which need additional validation for their performance. These parts are often commercial assemblies that are generally available to the electronic industry, and are utilised by the Test & Measurement coalition companies. Replacement of these assemblies, like-for-like, requires testing and validation prior to being integrated into the manufacturing process. The average time to find an alternative for medium complexity parts for production is reported to range from **6 to 12 months**.
- **High Complexity** parts are the complex sub-assemblies or parts that have a significant impact on performance of the company's products or play a critical role in overall safety of the products. These parts need to go through extensive validation for performance and/or compliances for varying regulations before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to purchase of parts for validation. The average time that it would take to find an alternative for high complexity parts for production is up to 1 year for additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take from **3 to 5 years**.

8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

- Authorisation
 - SVHC
 - Candidate list
 - Proposal inclusion Annex XIV
 - Annex XIV
- Restriction
 - Annex XVII
 - Registry of intentions
- Registration

2) Provide REACH-relevant information received through the supply chain.

Name of document: _____

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

- Yes. Consequences? _____
- No. Justification: Technically not feasible.

2. Can the substance named under 4.(A)1 be substituted?

- Yes.
 - Design changes:
 - Other materials:
 - Other substance:
- No.

Justification: Technically not feasible.

3. Give details on the reliability of substitutes (technical data + information): _____

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

- 1) Environmental impacts: _____
- 2) Health impacts: _____
- 3) Consumer safety impacts: _____

⇒ Do impacts of substitution outweigh benefits thereof?

Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

- a) Describe supply sources for substitutes: Please refer to point 7 of the submission form.
- b) Have you encountered problems with the availability? Describe: Please refer to point 7 of the submission form.
- c) Do you consider the price of the substitute to be a problem for the availability?
 Yes No
- d) What conditions need to be fulfilled to ensure the availability? _____

(D) Socio-economic impact of substitution:

⇒ What kind of economic effects do you consider related to substitution?

- Increase in direct production costs
- Increase in fixed costs
- Increase in overhead
- Possible social impacts within the EU
- Possible social impacts external to the EU
- Other: Possible economic impacts in the EU.

⇒ Provide sufficient evidence (third-party verified) to support your statement:

A thorough Socio-Economic Analysis has been performed by EPPA⁷ 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.

In line with the existing official guidance from ECHA on the preparation of the Socio-Economic Analysis,⁸ the 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 members as well as the relevant EEA supply chain and society are expected to face from the non-renewal of the exemption concerning electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors.

⁷ www.eppa.com

⁸ 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 ;

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

e.g., piezoelectronic devices, or in a glass or ceramic matrix compound, which would otherwise expire on 21 July 2024. Please see the respective SEA attached.

Overall, the main findings from the SEA conclude that, the total impact of a non-renewal is monetized in the range of 3.1 billion EUR and 4.3 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; substitution costs and social impacts (i.e., unemployment in the EU-27).

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

See Socio-Economic Analysis report attached.

10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:
