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
Name:	Meglena Mihova	E-Mail:	meglena.mihova@eppa.com
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:	_____

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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(a)

Proposed or existing wording: Existing.

"Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)"

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

Lead is a significant ingredient of the solder alloys used to electrically or physically join two elements. High Melting Point (HMP) solders are used for a wide variety of applications. Based on the application type, a lead amount of >85% is required to achieve the necessary melting temperature and to obtain other material properties.

As further outlined in this submission, there is no single substitute available that would be suitable for all the applications identified and match the technical performance of lead. 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 Test & Measurement Coalition therefore applies for the renewal of exemption 7(a) for the maximum renewal 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(a) 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 2.9 billion EUR and 4.1 billion EUR (conservative lower bound estimate).

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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 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 many 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.

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 performing those tests are 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 that 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(a).

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

Product Grouping	Equipment Types
Network Test, Security & Network Visability	GPIB
	Embedded Networks Hardware
	Industrial Communications Hardware
	Vision
Application-Specific Test Systems and Components	
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
	Dosemetry 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

Product Grouping	Equipment Types
	Programmable Power Supplies
	Embedded Controllers
	Remote Controllers
	Astronomical Equipment

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

☐ 1 ☐ 7
☐ 2 ☐ 8
☐ 3 ☒ 9
☐ 4 ☐ 10
☐ 5 ☐ 11
☐ 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: Lead in HMP solders is necessary to prevent solders within a component from melting during subsequent soldering operations. Solders that melt within the components can lead to open and unreliable joints and the shifting of features. Such failures at the component level will impact overall product reliability and the technical performance of products. This can, in turn, lead to intermittent failures that result in invalid measurement results from the finalised equipment. Lead in HMP solders allows for a higher standoff, improving processability and reliability, robust from higher Pb-free PCBA reflow temperatures.

4. Content of substance in homogeneous material (%weight): TMC members emphasized that the quantity of lead utilized in their homogeneous materials can contain between 85% and 95% lead by weight.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Approximately 25.5 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: Solders.

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?

High Melting Point (HMP) solders are used for a wide variety of applications. Examples of critical components that utilise this exemption and for which there are no alternative lead-free components, that satisfy the required performance characteristics, available on the market are:

- Industrial voltage regulators used in source-measure units and semiconductor characterisation systems.
- High performance network synchronizer clocks for industrial applications, used in oscilloscopes.
- High frequency resistors used in signal sources.

As noted above, lead in HMP solders is necessary to prevent solders within a component from melting during subsequent soldering operations. Lead in HMP solders allows for a higher standoff, improving processability and reliability, robust from higher Pb-free PCBA reflow temperatures.

(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 high melting temperature type solders provide superior properties and reliability compared to lead-free alternatives. Some of these properties and reasons for these required characteristics include:

- high melting point (>260°C) that is higher than standard eutectic solders. This prevents melting during secondary installations and the deterioration of the functionality of electrical parts;
- thermal conductivity ensures the reliability of electronic components due to heat dissipation;
- ductility is essential to join materials that have different coefficients of thermal expansion together in order to guarantee mechanical reliability;
- electrical conductivity is essential for electrical functionality;
- electrical resistivity;
- corrosion resistivity ensures reliability;
- resistance to thermal oxidation;
- appropriate oxidation nature prevents oxidation at the secondary mounting and guarantees reliability;
- wettability;
- manufacturability;
- reliability in a harsh environment.

Lead, as stated in the application of the RoHS Umbrella Industry from January 2020, is the only known element which satisfies all these properties. It is the combination of physical and chemical properties of the leaded alloys that is important. It is therefore not possible to pick a single property as a criterion of distinction under RoHS.

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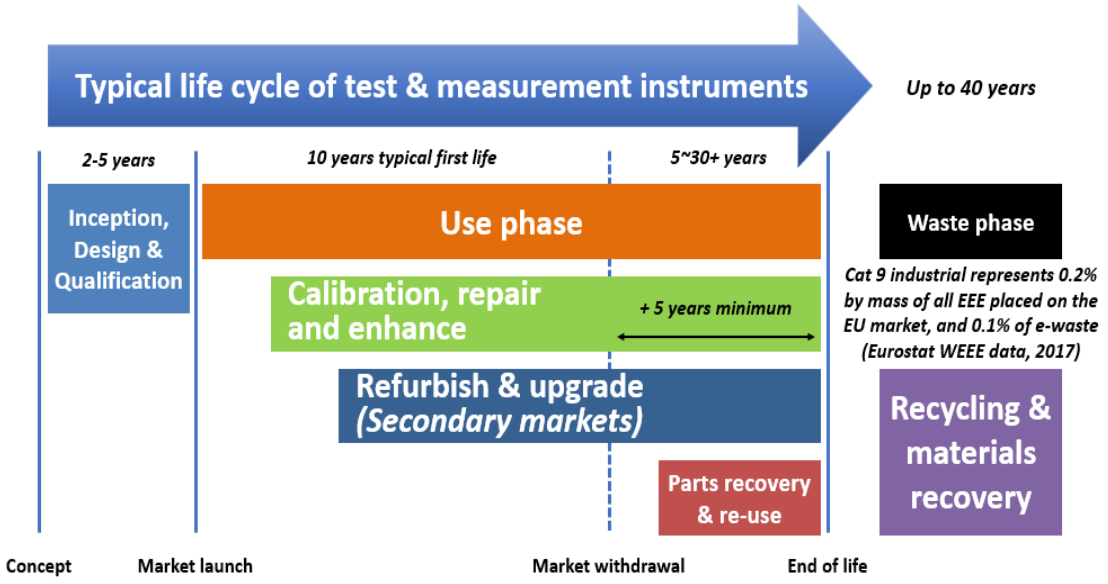
5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

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 _____

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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 is no single substitute available that would be suitable for all the applications identified and match the technical performance of lead. 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.

HMP solders, as noted above, are used for a wide variety of applications. There are potential substitutes for several applications; however, when the chemical and physical properties of substitutes are compared with HMP solder bonds, it becomes clear why these **substitutes are not broadly suitable**.

Alternatives must melt above the temperature for Pb-free solder reflow. Potential alternatives, and the main reason why these are not suitable for substitution, are listed here:

- **Standard lead-free solders** have a lower melting point than HMP lead solders but are also used for reflow soldering of PCBs. These would melt during reflow

and therefore cause bond failure when used for sealing components and for making bonds inside components or in modules.

- **Welding and brazing** are alternative bonding methods but require much higher temperatures. Brazing alloys typically melt at >400°C and welds are formed at >1,000°C. The silicon chip and the polymers used in electronic components will be destroyed at these temperatures.
- **Crimp connections** are often used in electrical equipment but suffer from a multitude of disadvantages. They cannot be used for sealing and their size precludes them from use inside small electronic components. Their main limitation is unreliability; repeated temperature cycles and vibrations cause very small movements between crimp and terminal that expose the underlying base metals that re-oxidise after their natural air-formed oxide is disrupted. The increase in the oxide amount can increase contact resistance to a value where the equipment no longer functions. The increased resistance in power circuits, for example, will cause heating that can ultimately lead to fires.

The following alternatives are also deemed unsuitable for substitution and replacement:

- **Mixed alloy pastes** that combine when melted to a new high temperature alloy. These are new to the market. Manufacturability and reliability of the resultant high temperature alloys has not been fully tested. These pastes could, in due time, achieve 70% efficacy.
- **Gold-tin braze** requires a particularly high melting temperature that can damage the components. This alternative has a limited 10% efficacy.
- **Sintered silver** is currently being tested but has not yet proven to be manufacturable and reliable. This alternative has a limited efficacy at 30%.

These alternatives are, for the reasons listed above, not suitable for substitution or replacement. They do not fulfil the same functions and do not have the same unique combinations of advantageous characteristics as lead.

(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.

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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.

Some combinations of substitutes will meet some criteria, but the significance of lead in HMP solders is its unique ability to satisfy a unique combination of essential properties. It is therefore not possible to pick a single property as a criterion of distinction under RoHS. Substitution is therefore not possible due to the numerous properties required from substitutes. Alternative technologies that match the ductility and strength of lead whilst retaining reliability during one or several reflow processes (melting of solder), which would otherwise weaken the bond, are not yet available.

The unavailability of alternatives for replacement and substitution asserted above echoes the findings of the RoHS exemption pack 22 conducted by the Öko-Institut published in February 2022. The information made available accordingly suggests that the substitution and elimination of lead in high melting temperature type solders is still technically and scientifically impracticable. The granting of exemption 7(a) should therefore be justified by Art. 5(1).

(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 mainly rely on their suppliers to find alternatives to the use of restricted substances since most of the components utilizing exemption 7(a) incorporated into T&M equipment are COTS parts. Therefore, meeting with suppliers to understand their (potential) alternatives, getting samples, measuring, and testing are part of the typical process to evaluate the suitability of potential alternatives. The process would then be followed by the validation of the potential suitable alternatives.

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 lead-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 to 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 complex sub-assembly parts and have a significant impact on the performance of the companies' products. These also have a critical role in the overall safety of the products. These parts need to go through extensive validation for performance and/or compliances, according to varying regulations, before the appropriate files can be updated and the proper competent authorities or regulatory bodies can be notified prior to the 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 of additional testing. Where the exemption directly impacts the performance of that component (e.g., a centrifuge rotor) the evaluation of the replacement could take 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 EPPA[1] 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,[2] 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 Coalition members as well as the relevant EEA supply chain and society are expected to face from the non-renewal of the lead (Pb) in high melting temperature type solders

[1] www.eppa.com

[2] 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

(i.e., lead-based alloys containing 85 % by weight or more lead), 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 2.9 billion EUR and 4.1 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; 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.

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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:
