# **Exemption Request Form**

Date of submission: 20 January 2023

#### 1. Name and contact details

#### 1) Name and contact details of applicant:

Company: <u>Te</u>	est & Measurement Coalition	Tel.:	<u>+32 2 735 82 30</u>
Name:	<u>Meglena Mihova</u>	E-Mail:	meglena.mihova@eppa.com
Function:	TMC Secretariat	Address:	<u>Place du Luxembourg 2,</u>
		<u>1050 Brus</u>	<u>ssels, Belgium</u>

# 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

 $\boxtimes$  Request for extension of existing exemption in

		1 1 1	•			
RDU	ii iast tar	noitaion	∩†	AVICTINA	avamntion	ın.
1100	Jucation	ucicuon	U.	CAISUING	exemption	

Provision of information referring to an existing specific exemption in:

Annex III Annex IV

No. of exemption in Annex III or IV where applicable:

Proposed or existing wording:

Duration where applicable:

Existing

6(a)

maximum validity period

"Lead as an alloying element in steel containing up to 0,35% lead by weight".

Other:

## 3. Summary of the exemption request / revocation request

Lead as an alloying element in steel containing up to 0.35% lead by weight is intrinsic for machining purposes in niche applications and as such used in numerous product groupings and equipment types of category 9 industrial Test & Measurement instruments.

As further outlined in this submission alternatives to lead for all type 6 exemptions are in development. However, the manufacturers of Test & Measurement Instruments are not component manufacturers and need to rely on component manufacturer supplies of parts for 75%+ of the components in their instruments. As and when such alternative parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of Category 9 equipment concerned. The applicants therefore believe a technical solution will and possibly is already available but it needs to be implemented for the specific usage, tried by the downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment.

Given the specific characteristics of Category 9 equipment and its long-life span and development cycles, the Test & Measurement Coalition applies for a renewal of the exemption 6(a) for the maximum validity period to allow for this process to take place.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socioeconomic impacts a non-renewal of exemption 6(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 2.1 billion EUR and 2.9 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 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 TMC 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 multimeters, 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 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 TMC manufacturers' 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 see below a table with the product groupings and equipment types relevant to exemption 6(a) for further illustration.

Equipment Types
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
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

Product Grouping	Equipment Types
	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 Visability	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

Product Grouping	Equipment Types
	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

Product Grouping	Equipment Types
	(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

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

□ 1	7
2	8 🗌
3	<b>9</b>
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

 $\boxtimes$  monitoring and control instruments in industry

in-vitro diagnostics

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

 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: <u>lead in steel provides a lubricant effect to the</u> <u>host material that results in a good chip crack performance and a smooth</u> <u>surface</u>
- 4. Content of substance in homogeneous material (%weight): <u>up to 35%</u>
- Amount of substance entering the EU market annually through application for which the exemption is requested: <u>approximately 9.82 kg</u> 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: steel alloy
- 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?

Lead as an alloying element in steel containing up to 0.35% lead by weight is intrinsic for machining purposes in niche applications. Different relevant types of low carbon steel that utilize lead for machining purposes include, as listed in the RoHS exemption pack 22 published in February 2022,<sup>1</sup> free-cutting steel, steel for quenching and tempering / heat treatable steel, and carburizing steel. Free-cutting steels are the most common usage scenario of leaded-steel alloys.

<sup>&</sup>lt;sup>1</sup> 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), published in February 2022. Available at: <u>link</u>.

The steel is used in a wide range of final applications within EEE, including fixed installations and finished products. High frequency / high power electromechanical relays, used in next generation performance oscilloscopes, is an example of a critical component that utilizes this exemption and for which there are no alternative lead-free components available on the market that satisfy the required performance characteristics.

The use of lead as an alloying element is essential if a variety of machining operations are required. Machining, as noted in the application of the Umbrella Project submitted in January 2020<sup>2</sup>, encompasses numerous production operations, including turning, grinding, rough forming, fine forming, (deep) drilling, and parting.

As noted in the RoHS exemption pack 22,<sup>3</sup> lead in steel provides a lubricant effect to the host material that results in a good chip crack performance and a smooth surface. For machining purposes, this allows for a higher cutting speed and enhances stability by reducing spindle stress. This property also allows for a longer tool life. Lead as an alloying element in steel significantly improves cutting performance. This is important, in turn, for the precision / fit of delicate machined components and for good mating surfaces. The machinability of lead and its ability to maintain or achieve specific combinations of mechanical properties after thermal treatment (hot workability) exemplify some of its advantageous properties.

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

Please refer to point (B).

# 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:

<sup>&</sup>lt;sup>2</sup> RoHS Umbrella Industry Project Exemption Application, published in January 2020. Available at: <u>link</u>.

<sup>&</sup>lt;sup>3</sup> 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), published in February 2022. Available at: <u>link</u>.

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 gualification 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:	
$\boxtimes$ Article is collected and sent without dismantli	ing for recycling
Article is collected and completely refurbishe	d for reuse
Article is collected and dismantled:	
The following parts are refurbished for	use as spare parts:
The following parts are subsequently re	ecycled:
Article cannot be recycled and is therefore:	
Sent for energy return	
3) Please provide information concerning stance present in EEE waste accumulate	
stance present in EEE waste accumulate	
stance present in EEE waste accumulate	
stance present in EEE waste accumulate No detailed data available In articles which are refurbished	
stance present in EEE waste accumulate No detailed data available In articles which are refurbished In articles which are recycled	

#### 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

The applicants recognize that alternatives to lead for all 6(x) type exemptions are in development. As stated elsewhere, the applicants are not component manufacturers and need to rely on component manufacturer supplies of parts for 75%+ of the components in their instruments. The custom-made parts are also largely constructed using component manufacturer parts which require those manufacturers to adapt and tool their processes to use the new technology upstream of the test and measurement instrument manufacturer. Nevertheless, the applicants believe it is likely that component manufacturers will gradually make available workable alternatives to the lead containing parts currently on the market. As and when such parts become available, they will be designed into new equipment that is developed in a cycle of 7-10 years depending on the type of Category 9 equipment concerned. This process is well-established to avoid reliance upon a specific RoHS exemption to produced compliant equipment. What is needed, however, is for an exemption to be available for equipment that is nearing final design (3-5 years development) and equipment currently marketed. Substitution – whilst feasible – is considerably more onerous and complex in those cases than for new, yet to be designed, equipment or for equipment undergoing a complete redesign. The assessment below therefore focusses on the scenario of equipment in current development for marketing in 2024 (when the exemption expires) and equipment currently placed on the EU market that will not be discontinued prior to 2024, where current design includes lead-containing components requiring exemption 6(a) which would need to be designed out and substituted. The time required for this process will indicate the need and length of an exemption for Category 9 Industrial equipment.

A single assessment of the performance of the alternatives is not possible because of the ubiquity of the alternative use. Each use must be considered in and of itself to validate if an alternative would work as well as or better than the component made currently using the exemption. One commonality is the component suppliers need to be able to tool the alternative material into qualified components. The applicant believes a technical solution will and possibly is already available but must become widely implemented for the specific usage, technical evaluated by the downstream user (e.g., producer, manufacturer) of the component, and then tested in the full individual piece of equipment.

(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.

The companies have indicated that there are currently no suitable alternatives that meet the performance expectations of their customers. However, it is foreseeable that such alternatives will be made available in the coming years but the implementation for the different uses will be very gradual and implementation is not likely to be linear. Members of the Test & Measurement Coalition have pointed out that they principally rely on their component suppliers to find alternatives since most of the exemptions used in those components are not produced by the supplier but are bought off-the-shelf from their 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 are 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. However, the companies noted the impacts deriving from their suppliers as, depending on the complexity, there can be little to significant time and resources needed to validate alternatives.

The companies reported that the validation period would take a minimum of 6 months and up to a year after the delivery of suitable alternative-containing components 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 material, additional safety and EMC testing and performance validation period would likely be required for each redesigned product previously reliant on the exemption. The test and measurement equipment manufacturers estimate this to be applicable to 20-25% of components containing the alternative materials. Such redesign activity would add another year to test and implement the alternative material in the bespoke component.

All this validation activity incurs 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 from a supplier, this part must be gualified for use by the Category 9 manufacturer by performing a variety of additional 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 diverts resources from other projects and increases the cost to ensure continued availability of these products. This validation and testing process varies according to part complexity; 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 integration 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.

What makes substituting exemption 6(b) challenging is the ubiquity of the application of the exemption. The uses are very different and no single substitution approach will satisfy a complete replacement of lead-containing parts using this exemption. The key technical characteristics – such as tooling ability – are not meaningful in the function of the component in the final equipment as such. This can be a precision part of an oscilloscope or a very ordinary rotor part of a cooling fan, substitution is therefore very arduous as replacing one part does not eliminate the need for the exemption. The applicants again underline that they concede alternatives are in development, but this does not change the need for the exemption to be maintained in particular for Category 9 equipment for which substituting single parts involves thousands of different equipment with long development and redesign cycles.

The substitution plan below presumes a hypothetical situation where, for a particular Category 9 equipment, the substitution of all components using the 6(a) exemption would be planned. Right now, the applicants are not aware of specific components able to substitute all parts. But, for the sake of argument, the substitution plan presumes that component manufacturers come forward

with a technology that would substitute lead in all parts using these exemptions. The substitution plan presumes:

- The component manufacturer has developed an alternative technology that they propose to implement for the components delivered to the Category 9 OEMs;
- For simplicities sake it is presumed that the technology is universally implementable and that component manufacturers will make the new components available for testing in rapid succession (optimistic scenario):
- It is presumed that the alternative technology is available as of 1/1/2023 but has not yet been implemented for all uses of components currently having lead as an alloy;
- <u>As a realistic worst-case scenario, the equipment that is chosen for</u> <u>substitution is in final stages of development for launch in 2024 (i.e., at</u> <u>expiry of the exemptions);</u>
- <u>The application is presumed to be used in 10 discrete components that</u> <u>break down as follows:</u>
  - <u>6 low complexity parts;</u>
  - <u>3 medium complexity parts;</u>
  - <u>1 high complexity part that involves custom or bespoke design</u> by the Category 9 OEM;
- <u>Companies reported that the exemption is used in a range of 59% to 61% of all equipment families marketed by Category 9 OEMs</u>; <u>This means ca. 36,000 equipment are concerned by the exemption of which 3,600 are likely to be at the launch stage in 2024</u>;
- For reference, the capacity to reengineer (new product introduction, new generation release, and compliance to legal requirements) of the whole category 9 sector is 300 different pieces of equipment per year.
- <u>As a reminder, Category 9 OEMs have 1 engineer available per</u> equipment family marketed. These engineers are not easily interchangeable due to the hugely varying types of equipment marketed.

Substitution milestones:

The substitution of lead containing components using exemption 6(a) can be managed along the following milestones:

- 1) <u>Component manufacturer & Category 9 OEM collaborate for the development of the discrete components required in the equipment;</u>
  - a. <u>Communication of equipment specification requirements to</u> <u>component manufacturer;</u>
  - b. Alignment on technology with component manufacturer;

- c. Component manufacturer develops new component without lead;
- d. Trial deliveries of components commences;
- 2) <u>Testing and viability of component design for specific Category 9 equipment</u> <u>family;</u>
  - a. <u>Testing of single component starts (outside of application in equipment);</u>
  - b. Lifetime stability and longevity testing (7x time compression);
  - c. Redesign phase for failed components;
  - d. Scale up manufacturing by component maker;
- 3) Design in components to Category 9 equipment families;
  - a. <u>Three stages of 500 equipment families (cannot be done concurrently);</u>
  - b. Testing for unexpected equipment interference;
  - c. <u>Lifetime testing in equipment setting;</u>
- 4) Roll out of compliant equipment.

Although the timeline that follows from above may look long, it should be considered that many component manufacturers are not even aware exactly how many of their components use the exemption. This correlates with the Category 9 OEMs who are equally unaware of the full extent of the use of this very common exemption. The amounts of lead are so small and close to the RoHS legal limit of 0.1% that in some cases the component manufacture render it difficult to decide whether the limits are exceeded at homogenous material level.

	COMPONENT MANUFACTURER STAGE	OEM COMPONE	NT STAGE	OEM DEVICE STAGE	ROLLOUT
an 1 - Jul 1	1 Specification of components				
Jul	1 - Oct 31 Det Alignment with components ma	nufacturer			
Ju	ul 3 - Jul 1 🔪 Compo	nent manufacturer develops part			
	Jul 1 - Dec 31 🚬	Trial deliveries			
	Jan 1 - Jul 1 🔰	OEM testing of component function	nality low complexity		
	Jan 1 - Dec 31	OEM testing of component			
	Jan 1 - Dec 31 🔰	OEM testin	of component functionality high	n complexity	
		Dec 31 🚬	Life time testi		
	1 - 1 lut	Dec 31	· · · · · · · · · · · · · · · · · · ·	Redesign of failed components (thro	The second s
			Jan 1 - Jul 1	Stage 1 device	design (500 families)
				Jul 1 - Jul 1 🔪	Stage 2 device design (500 families - presumed faster)
то	DDAY			Jul 1 - Dec 31	Stage 3 device design (500 families - slower to cover 3xstandard deviation)
	2023 2024 2025	2026 2027 2028	2029 2030	2031 2032 2033	2034 <b>203</b> 4
	Start of the project			Scale-up for manufacturing Jun 1 First Indu: Productio Jul 31	

The conclusion on the suitability and availability of alternatives is that whilst substitution is possible, it will require time. Time that is likely to exceed the redesign cycle of equipment which as of today are already being developed without use of the exemption. There is therefore a continued need for a 7-year additional exemption for Category 9 to allow the phasing out of the older equipment for newly designed ones which are lead-free. At this stage of the availability of alternatives, there is no material gain for the environment in restricting the alternative compared to the huge costs involved in gradual substitution of existing equipment.

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

Please refer to point (A).

#### 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

- Candidate list
- Proposal inclusion Annex XIV
- Annex XIV

Restriction

Annex XVII

Registry of intentions

Registration

 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: For the time being technically not feasible, but over time alternative components will become available.

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

Yes.	
105.	

Design changes:
Other materials:
Other substance:

🛛 No.

Justification: <u>For the time being technically not feasible</u>, but over time alternative components will become available.

- 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: <u>Please refer to point 7 of the</u> <u>submission form.</u>
- b) Have you encountered problems with the availability? Describe: <u>Please</u> 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? <u>Please refer</u> to point 7 of the submission form.

#### (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
  - $\boxtimes$  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<sup>4</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.

In line with the existing official guidance from ECHA on the preparation of the Socio-Economic Analysis,<sup>5</sup> the SEA therefore gathers technical and economic information to describe ex-ante in both gualitative and (if feasible) guantitative terms the (orders of magnitude of) socio-economic impacts TMC ell 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. Please see the respective SEA attached.

Overall, the main findings from the SEA conclude that, the total impact of a nonrenewal is monetized in the range of 2.1 billion EUR and 2.9 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account).

### 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:

<sup>&</sup>lt;sup>4</sup> <u>www.eppa.com</u>

<sup>&</sup>lt;sup>5</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 ; 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