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: 34

Proposed or existing wording: Existing.

"Lead in cermet-based trimmer potentiometer elements."

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

The cermet potentiometer is typically used to calibrate a specific measurement or control parameter so that the final product can meet that exacting measurement resolution or output control parameter that the application requires. Thick film is a resistive and conductive film greater than 0.0001” thick resulting from firing a paste or ink that has been deposited on a ceramic substrate. The PbO within the glass substrate with the resistive ink allows the thick film to be fired at lower temperatures. This makes the resultant cermet to have the thermal characteristics and resistive value stability of the ceramic material and enable the electric resistance of the material to remain stable under changing temperatures.

Of the alternates investigated, most were eliminated either because they were also toxic or had a melting point too high for current substrate materials and the manufacturing processes employed. Only Sodium Bismuth Titanate has the potential to be used but would require further investigation. Bismuth Oxide is another alternate though the toxicity needs to be assessed to see if it would be a regrettable substitution. However, in both cases we currently have not identified any alternates cermet resistor that employ these materials and are commercially available.

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 34 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 0.3 billion EUR and 1 billion EUR (public range; 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 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 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 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 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 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.

Types of products that utilize these trimming cermet pots:

- Relative Humidity sensors
- Power supplies
- Dosimetry Readers
- Temperature controller modules
- Sample Prep Liquid Chromatography
- Liquid Chromatography / Mass Spectrometry
- CO2 Incubators
- Environmental Chambers
- Minimum Inhibitory Concentration (MIC) Lab test automation
- Spectroscopy Equipment
- Electron Microscopes

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:
   The PbO within the glass substrate with the resistive ink allows the thick film to be fired at lower temperatures. This makes the resultant cermet to have the thermal characteristics and resistive value stability of the ceramic material and enable the electric resistance of the material to remain stable under changing temperatures.

4. Content of substance in homogeneous material (%weight): 44.614 %w/w

5. Amount of substance entering the EU market annually through application for which the exemption is requested: <10g.

   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: Lead in cermet-based trimmer potentiometer elements.

7. Environmental Assessment: _____
   LCA: ☐ Yes
   ☒No

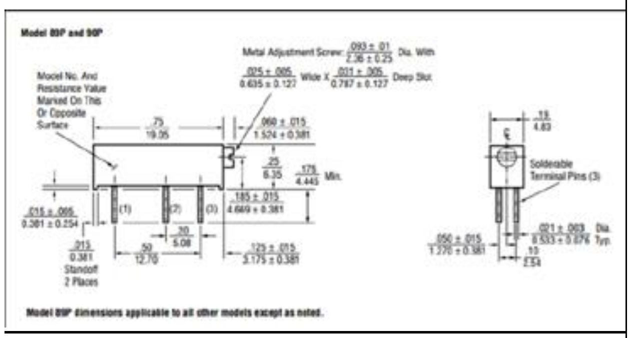
(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

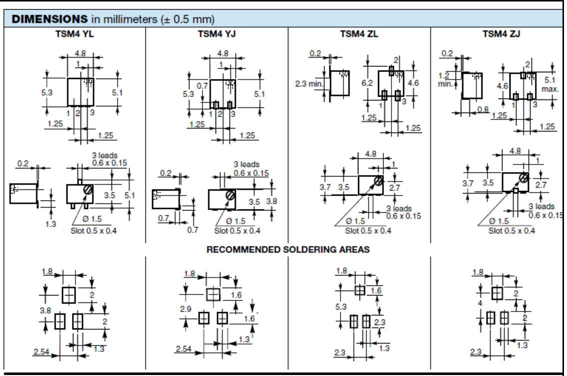
The cermet potentiometer is typically used to calibrate a specific measurement or control parameter so that the final product can meet that exacting measurement resolution or output control parameter that the application requires. Whenever there is a critical measurement that can vary production unit to production unit (because of component tolerances) then precise calibration adjustment is required to each product during the manufacturing process. Once calibrated in the factory, that setting must remain stable during storage, transport and use for the installed life of the product, only checked during annual calibration or the preventative maintenance program for the product in question. A drift in a measurement or control parameter would lead to previous passing results being questioned or repeated and the potential recall of products manufactured by the processors utilizing instrumentation relying on these cermet potentiometers that had been previously released.

The components that utilize this specific exemption are used as a calibration tool for test and measurement boards T&M companies specifically design, and also used by T&M instrument vendors for critical components they provide to the T&M Coalition (like switch mode power supplies or modular temperature controllers or calibratable probes). This includes:

1. Multi-turn trimmers

These are PCB mounted for both plated through and surface mount application, so any replacements would need to match the footprint or require a complete PCB re-layout to accommodate any footprint alterations.





As these are used for precise parameter calibrations which will need to be adjusted, corrected during periodic, on site, calibrations, then the profile of the trimming pot is also critical. To enable access to the trimming screw during an energized service phase, openings in protective enclosures have sometimes been aligned based on the trimming pot profile to allow adjustments to be made safely, especially where hazardous voltages are present. T&M companies have already sought out alternatives for these trimming devices, but all that matched our criteria, regardless of the manufacturer utilize this same exemption.

Parameter	Range	Notes
Electrical		
Resistance, tolerance, input voltage, slider current, etc.	Varied range based on application in question	Easiest to be able to select a like for like comparison
Dielectric strength, insulation resistance	Varied range based on application in question	Easiest to be able to select a like for like comparison
Resolution	Essentially infinite	This infinitesimal adjustment is critical.
Contact resistance variation, maximum	1% or 1Ω	The PbO in the glass substrate makes this possible
Environmental		
Temperature Coefficient	±100 ppm/°C	The PbO in the glass substrate makes this possible
Operating Temperature range	-55°C to +125°C	These parameters ensure stability through the ISTA transport requirements
Thermal Shock	5 cycles, -55°C to +125°C	
Shock, 6ms sawtooth	100G's	
Vibration	20G's	

Types of products that utilize these trimming cermet pots:

- Relative Humidity sensors
- Power supplies
- Dosimetry Readers
- Temperature controller modules
- Sample Prep Liquid Chromatography
- Liquid Chromatography / Mass Spectrometry
- CO_2 Incubators
- Environmental Chambers
- Minimum Inhibitory Concentration (MIC) Lab test automation
- Spectroscopy Equipment
- Electron Microscopes

When factory set calibrations are relied upon – for example CO_2 incubators and environmental chambers that use RH sensors that utilize these trim pots, these calibration parameters must retain their calibration point while in storage and transport – including the ISTA transport vibration tests and thermo cycling with transport temperatures up to 70°C. Furthermore, for incubators they operate in laboratory environments at up to 33°C and relative humidity up to 80% RH and have an internal decontamination temperature routine that operates at up to 90°C and yet must still maintain the calibration accuracy for critical incubation (e.g., IVF) at +/- 0.5°C.

Based on the full material disclosure included below, the RoHS exemption 34 Annex III part is used specifically as PbO within the glass matrix of the conductor (the potentiometer sweep arm) and the resistor itself which represents only 0.14% of the mass of the potentiometer. Out of a total mass of 1.2g per cermet potentiometer, the PbO totals 0.7mg. The types of products listed above are typically cap expenditure purchases and represent < 3K products sold into the EU, so the total PbO import is **< 10g** per year for Cat 9, Industrial.

Full material disclosure for the most common cermet trim pot family used:

Model 89LF BOM-style material declaration. BI Technologies Corporation **8/16/2010**

No content here is banned per E.U. R.o.H.S.. Average mass of 89LF trimmer is 1.2 grams each. Prepared by Eric Arnold (714) 447-2565
Weights above 1 milligram rounded to the nearest mg. Values less than 1 milligram given in scientific notation.

Sub-component	Material	% of total mass	Substance name	CAS #	Substance Weight (grams)	Special classification
Housing	PBT blend	33.0%	PBT	26062-94-2	0.303	
			Fiberglass	65997-17-3	0.081	
			SbO	1309-64-4	0.020	Fire retardant
Shaft	Brass	28.8%	Cu	7440-50-8	0.217	
			Zn	7440-66-6	0.125	
			Pb in brass	7439-92-1	0.011	Pb in copper alloy (RoHS exempt)
Slider block	PBT blend	2.1%	PBT	009002-84-0	0.019	
			Fiberglass	65997-17-3	0.006	
			PTFE	009002-84-0	0.001	
Contact	Cu alloy wire	0.13%	Cu	7440-50-8	8.43E-04	
			Zn	7440-66-6	4.14E-04	
			Ni	7440-02-0	2.76E-04	
	Nickel alloy bar	0.08%	Cu	7440-50-8	5.00E-07	
			Ni	7440-02-0	8.46E-04	
			C	7440-44-0	6.00E-07	
			Mn	7439-96-5	2.50E-06	
			Fe	7439-89-6	1.50E-04	
			S	7704-34-9	5.00E-07	
			Si	7440-21-3	5.00E-08	
Terminals	Cu wire	4.9%	Cu	7440-50-8	0.060	
	Sn plating	0.002%	Sn	7440-31-5	1.73E-05	
Potting	Epoxy	11.0%	SiO2, amorphous	7631-86-9	0.007	
			modified aliphatic polyamine	trade secret	0.027	
			hydantoin epoxy resin	15336-82-0	0.007	
			epichlorohydrin / polyglycol epoxy resin	26142-30-3	0.007	
			epichlorohydrin/bisphenol A epoxy resin	unknown	0.081	BPA
			cycloaliphatic epoxy resin	2386-87-0	0.007	
Substrate	Alumina	19.8%	Al2O3	1344-28-1	0.233	
			SiO2, amorphous	7631-86-9	2.42E-03	
			TiO2	13463-67-7	1.21E-03	
			FeO2	1345-25-1	0.001	
			MnO2	1313-13-9	0.002	
			MgO	1309-48-4	0.001	
			CaO	1305-78-8	0.001	
Conductor	AgPd thick film	0.05%	Al2O3	1344-28-1	4.34E-06	
			SiO2, amorphous	7631-86-9	1.90E-05	
			TiO2	13463-67-7	4.34E-06	
			PbO	1317-36-8	2.59E-05	RoHS exemption 34
			ZnO	1314-13-2	4.71E-06	
			B2O3	1303-86-2	1.60E-06	
			ZrO2	1314-23-4	3.84E-07	
			BaO	1304-28-5	4.93E-06	
			Ag	7440-22-4	5.17E-04	
			Pd	7440-05-3	5.76E-05	
Resistor	Ruthenate thick film	0.09%	Al2O3	1344-28-1	1.47E-05	
			SiO2, amorphous	7631-86-9	1.24E-04	
			TiO2	13463-67-7	1.47E-05	
			MnO2	1313-13-9	6.66E-06	
			PbO	1317-36-8	3.24E-04	RoHS exemption 34
			ZnO	1314-13-2	3.54E-05	
			B2O3	1303-86-2	4.14E-05	
			ZrO2	1314-23-4	9.94E-06	
			BaO	1304-28-5	1.68E-05	
			Ag	7440-22-4	4.00E-05	
			Pd	7440-05-3	5.10E-05	
			Steatite	14807-96-6	2.22E-06	
			Bi2Ru2O6	unknown	5.00E-05	
			Pb2Ru2O6+x	unknown	3.55E-04	RoHS exemption 34
			RuO2	12036-10-1	2.33E-05	

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

The physical function of lead in the components that are utilised by the T&M products are like those outlined in a previous exemption renewal request for exemption 7(c)-I submitted by Bourns Inc. and the Umbrella Project:[1]

Thick film is a resistive and conductive film greater than 0.0001" thick resulting from firing a paste or ink that has been deposited on a ceramic substrate. The PbO within the glass substrate with the resistive ink allows the thick film to be fired at lower temperatures. This makes the resultant cermet to have the thermal characteristics and resistive value stability of the ceramic material and enable the electric resistance of the material to remain stable under changing temperatures.

Specifically, the lead containing cermet potentiometers have the following advantageous characteristics:[2]

- Long lifetime, typically up to 50,000 rotation cycles (non-lead solutions are usually rated at 25,000 cycles)
- Low temperature coefficient (TC). The TC for a typical cermet potentiometer is 150 ppm/°C, which is lower than other types of potentiometers.
- High level of heat dissipation
- Wide operating temperature range (-55°C to +125°C)
- Higher wattage rating, e.g., 3 watts
- Low reactance at high maximum frequency
- Good resolution (resolution is the smallest possible change in resistance ratio)
- Low electrical noise when resistance is adjusted
- Small size enabling use in high density microelectronic circuits
- Preliminary tests with LF inks suggest that a lubricant is necessary. However, even with a lubricant, the same performance will not be reached with all ohmic values.

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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

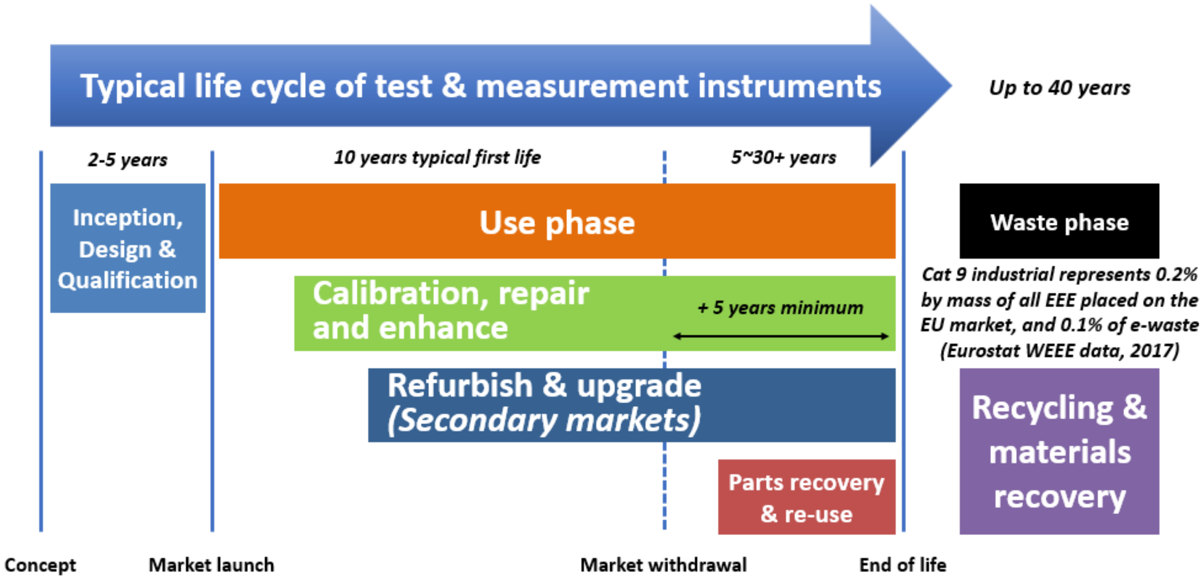
[1] Previous RoHS exemptions requests are publicly available and downloadable from the EU Commission webpages. Available at: https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

[2] Ibid.

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

There are certain studies that have been conducted to investigate the suitability of alternative substances. As outlined in renewal application for exemption 34 by the Umbrella Project, comparisons between a Thick-Film (Cermet) Device and a Polymer Thick-Film (PTF) Device, which is the current closest alternate substrate material for a potentiometer with infinite resolution, have been made (as detailed below):

ELECTRICAL CHARACTERISTIC	Cermet	PTF	Notes
STANDARD RESISTANCE RANGE	**10Ω to 1MΩ**	**1kΩ to 1MΩ**	
RESISTANCE TOLERANCE (TRIMMED)	**±0.5%**	**±1%**	
INDEPENDENT LINEARITY	**Down to ±0.5%**	**Down to ±2%**	
RESISTIVITY	**Down to 3μΩ.cm**	**10μΩ.cm**	
ENVIRONMENTAL CHARACTERISTIC	**Cermet**	**PTF**	**Notes**
POWER RATING	**0.5W**	**0.2W**	
TEMPERATURE RANGE	**-55°C to +150°C**	**-10°C to +125°C**	
HUMIDITY[3]	**± 1% TRS**	**± 10% TRS**	**See Footnote**
VIBRATION[4]	**± 1% TRS**	**± 2% TRS**	**See Footnote**
SHOCK[5]	**± 1% TRS**	**± 2% TRS**	**See Footnote**

The environmental characteristics alone make a PTF unsuitable for many trim pot applications that can be used in a laboratory environment.

In addition, the Test & Measurement Coalition has conducted an AI assisted research on potential other suitable alternatives.

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[3] Cermet is tested to MIL-STD-202 Method 106 which cycles from 25% RH to 100%RH, PTF is only tested at 50%RH

[4] Cermet is tested at 30G vibration, PTF is only tested at 15G vibration

[5] Cermet is tested at 100G shock, PTF is only tested at 30G shock

(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.

EPPA and TMC conducted a study with FINDEST to search for a suitable replacement for lead in potentiometer devices or similar electronics components where infinite sliding variability is the primary function in question. There is an extensive list of secondary constraints which includes electrical and environmental properties such as long lifetime, low temperature coefficient, wide operating temperatures, high wattage and high level of heat dissipation. The objective of the AI search was to identify a material capable of replacing lead oxide that would match the environmental stability of lead oxide (heat, shock, vibration, etc.) while avoiding a redesign of the trimmer parts by the changing material. The constraints were:

- Material which can enable infinitely variable contact resistance.
- Match electrical stability of lead oxide; resistance, resolution, etc.
- Cermet materials as a substrate.
- Non-toxic to avoid any regrettable substitutions.
- Melting point.

The reference substrate material that is already suitable for the mechanical and vibration resistance and is currently used in a PbO based cermet potentiometers is Aluminium Nitride. To substitute both the substrate and the oxide would have made the search an order of magnitude more complex and so was not approached at this time. The material properties for Aluminium Nitride (AlN) are:

- High thermal conductivity – up to 321 W/(m.K)
- An electrical insulator
- Temperature stability, melting point:
    - In inert atmospheres 2200°C
    - In a vacuum 1800°C
    - In air, 1370°C, assuming that a 5-10 nm surface oxide layer has formed which happens at room temperature when it is exposed to air

Material	Toxic (Y/N)	Melting point	Notes
Lead oxide (PbO)	Y	888°C	Current metal oxide in use today.
Barium Oxide BaO	Y	1923°C	Melting point too high and toxic, so a regrettable substitution.
Zinc oxide (ZnO)	N	1975°C	Melting point too high, so would need an alternate substrate or a new manufacturing process that employed an inert atmosphere.
Lithium Oxide (Li_2O)	Y	1438°C	Melting point too high and toxic, so a regrettable substitution.
Magnesium Oxide (MgO)	N	2852°C	Melting point too high, so would need an alternate substrate
Indium Tin Oxide (ITO)	Y	1526 - 1926°C	Melting point too high and toxic, so a regrettable substitution.
Iron / Ferric Oxide (Fe_2O_3)	N	1539°C	Melting point too high, so would need an alternate substrate or a new manufacturing process that employed an inert atmosphere or a vacuum.
Strontium Oxide (SrO)	Y	2531°C	Melting point too high and toxic, so a regrettable substitution.
Cerium Oxide (CeO_2)	Y	2400°C	Melting point too high and toxic, so a regrettable substitution.
Bismuth Oxide (Bi_2O_3)	Y	817°C	Though a potential substitute, the toxicity may make it a regrettable one.
Sodium Bismuth Titanate (NBT)	N	1290°C	May be a viable alternate
Calcium Titanate Perovskite ($CaTiO_3$)	Y	1975°C	Melting point too high and toxic, so a regrettable substitution.
Silicon Dioxide (SiO_2)	N	1610°C	Melting point too high, so would need an alternate substrate or a new manufacturing process that employed an inert atmosphere or a vacuum.
Lanthanum Oxide (La_2O_3)	N	2315°C	Melting point too high, so would need an alternate substrate.
Lignocellulose-lead oxide (LC/PbO_2)	Y	-	A regrettable substitution as lead dioxide is a probable carcinogen.

Lead-free halide perovskites ($Cs_3Sb_2I_9$)			Too early to report.
Potassium sodium niobate (KNN)	Y	-	Toxic, and current KNN-based ceramics have a deteriorative microstructure that restricts further developments.

Summary:

Of the alternates investigated, most were eliminated either because they were also toxic or had a melting point too high for current substrate materials and the manufacturing processes employed. Only Sodium Bismuth Titanate has the potential to be used but would require further investigation. Bismuth Oxide is another alternate though the toxicity needs to be assessed to see if it would be a regrettable substitution. However, in both cases we currently have not identified any alternates cermet resistor that employ these materials and are commercially available.

(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 since most of the exemptions used in their products are not produced on-site by the company but bought off-the-shelf from suppliers. Therefore, meeting with suppliers to understand their (potential) alternatives, getting samples, measuring, and testing is the typical process to evaluate the suitability of potential alternatives which can take up to 4 years, as reported by the companies. The process would then be followed by the validation of the potential suitable alternatives accompanied by testing done by the manufacturers by the finished T&M equipment with the validation of the functionality and performance being their responsibility as well. 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 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.

Taking everything into consideration, the substitution process would take a minimum of 5-7 years.

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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[6] 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,[7] 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

[6] www.eppa.com

[7] 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

members as well as the relevant EEA supply chain and society are expected to face from the non-renewal of the lead (Pb) in cermet-based trimmer potentiometer elements, 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 0.3 billion EUR and 1 billion EUR (public range; conservative estimates in net losses), 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:

_____
