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:	_____

---

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: 13(b)

Proposed or existing wording: Existing.

"Cadmium and Lead used in filter glasses and glasses used for reflectance standards."

Duration where applicable: Maxiumum validity period.

☐ Other: _____

3. Summary of the exemption request / revocation request

Exemption 13(b) is an exemption to allow the addition of cadmium (Cd) and lead (Pb) into glass specifically for the creation of filters and reflectance standards. Category 9 products use glass filters within the optical design for highly specialist applications. These optical systems are part of sensitive measuring apparatus used throughout a wide variety of applications and industries, where highly sensitive accurate measurements are needed.

As further outlined in this submission, to the best of knowledge of the Test & Measurement Coalition no alternatives have been developed for the applications described in this exemption renewal request and other applications that require cadmium and lead filter glasses. The Test & Measurement Coalition therefore applies for a renewal of the exemption 13(b) for the maximum validity period.

A thorough Socio-Economic Analysis was conducted in addition to the technical assessment and attached to this submission, further illustrating the negative socio-economic impacts a non-renewal of exemption 13(b) 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 1 billion EUR and 1.5 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 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 13(b).

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

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

☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☒ 9
☐ 10
☐ 11

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 glass is typically used in instruments where a flat transmission is required with minimum chromatic aberration. Lead glass has optical transmission from the UV through the visible and the NIR, especially important for devices that utilise this extended spectrum such as universal measurement spectrometers and fluorescence microscopy.

   Cadmium glasses are exploited as long pass filters used to eliminate short wavelength light. The composition of the glass is varied to tune the cut-off frequency for specific applications. Without effective long-pass filters the measured signal would be swamped by the incident light, and accurate measurements would be impossible.

4. Content of substance in homogeneous material (%weight): Cadmium-based filter glass typically contains approximately 0.4% cadmium by weight and lead-based filter glass contains between 13% and 28% of lead by weight. Overall, through application for which the exemption is requested.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Approximately 0.08 kg of Cd and 0.58 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: Cadmium and lead glass optics.

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

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

Exemption 13(b) is an exemption to allow the addition of cadmium (Cd) and lead (Pb) into glass specifically for the creation of filters and reflectance standards. Category 9 products use glass filters within the optical design for highly specialist applications. These optical systems are part of sensitive measuring apparatus used throughout a wide variety of applications and industries, where highly sensitive accurate measurements are needed.

Examples of instruments that utilise cadmium and lead glass optics include:

- **Atomic Absorption Spectrometers** are a fundamental spectro-analytical technology used to detect and determine the concentration of an element in a sample. These are used in a wide variety of applications including pharmacology, biophysics, archaeology, toxicology, environmental waste monitoring, and many others.
- **Universal measurement spectrometers (UV-VIS-NIR wavelengths)** are another spectro-analytical tool used to determine the existence of specific molecules within samples. Such spectrometers are used in almost every analytical and basic chemical and biological laboratory worldwide. Use examples include quality control testing within the pharmaceutical industry, measuring the pigments of paints on original artistic works and archaeological artefacts, measuring the kinetics of molecular reactions, analysing nitrates within water samples, detecting banned substances in sports, and assessing solar cell material.
- **Multimode microplate readers** are used to detect the biological, chemical, and physical events in mircotitre plates. They are commonly used in cellular biology for researching biological processes.
- **Detection systems for liquid Chromatography** is a technique for separating a molecular distribution by size. It is typically used for separating protein mixtures. It is widely used in life sciences and bioindustry.

- **Spectroradiometers** analyse the absorption of light through a sample. This is the principle between molecular and atomic absorption; however, these spectrometers are used for more generic analysis of liquids and solids. They can be used to analyse anything from optical elements, protein purification, properties ranging from inks to solar cells, and hundreds of other applications. Spectroradiometers typically assess light absorption beyond the visible spectrum, both in the Ultra-Violet (UV) and Near-Infra-Red (NIR) bands.
- **Laser Interferometer Systems** are highly precise position monitoring systems. They utilise the interference properties of coherent light in order to monitor the position of objects to an accuracy shorter than the wavelength of light. These systems are used extensively within electro-mechanical products where precise position is needed.
- **Fluorescence microscopy** is an optical microscope that also measures the fluorescence of a sample. The microscope is equipped with one or more light sources (typically lasers) for excitation of the fluorophores. Such microscopes require precise optical filtering and control to provide both visible and fluorescence images and for the removal of the excitation light sources. Fluorescence microscopy can also be coupled with confocal microscopy to provide three-dimensional fluorescence imaging. Fluorescence microscopy is used across a huge variety of subject areas both with naturally fluorescent materials (autofluorescence) and with the use of fluorescent markers (Figure 1).

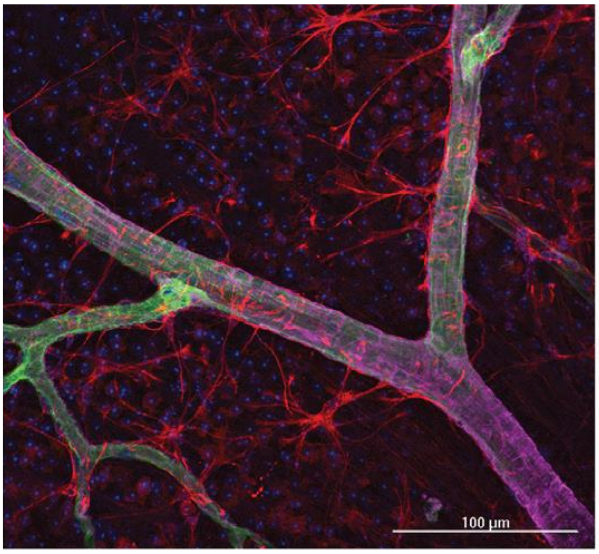


Figure 1. Fluorescence microscopy of Astrocytes (cells supporting nerve cells) within a mouse retina.

The optical systems within these instruments are typically complex, with multiple optical elements at each stage (source/sample/detection) to optimise the measurement (Figure 2). Optical filters are a critical part of these instruments. Filters are used either to remove unwanted parts of the light spectrum and for splitting the light beam where the light is separated into multiple optical paths. The exact characteristic of the filter is therefore critical to remove unwanted frequencies but also to work in harmony with the designed optical system. As such, any change in the optical characteristics of one element of the optical system will require a redesign and re-validation of the entire optical system and device.

The addition of lead and cadmium into glass provides unique characteristics that are not replicated by other glasses. Lead glass is typically used in instruments where a flat transmission is required with minimum chromatic aberration. Lead glass (Figure 3) has optical transmission from the UV through the visible and the NIR, especially important for devices that utilise this extended spectrum such as universal measurement spectrometers and fluorescence microscopy.

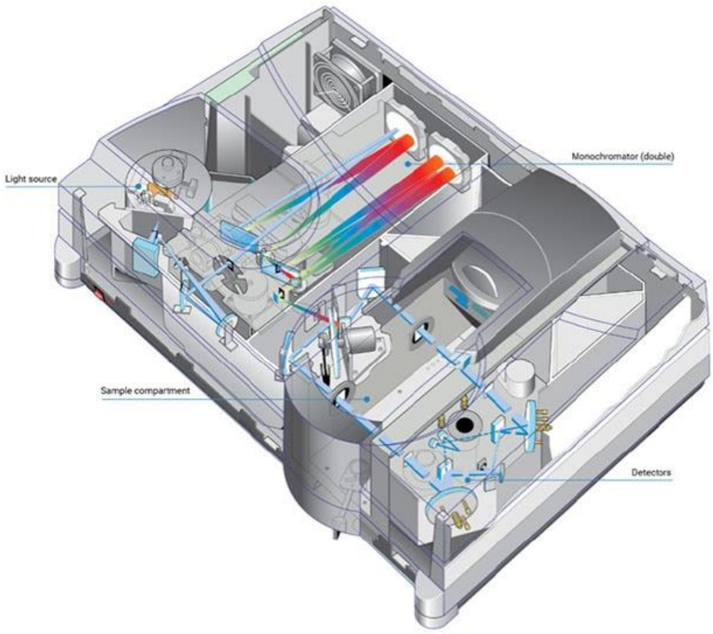


Figure 2. Typical optical configuration within a spectrometer instrument. Optical elements are required for the light source (top left), sample chamber (centre), and detection elements (bottom right). The entire optical system is designed to provide the accuracy and precision required for the measurement.

Cadmium glasses are exploited as long pass filters used to eliminate short wavelength light. The composition of the glass is varied to tune the cut-off frequency for specific applications. Figure 3 shows a selection of cadmium glasses with cut-off frequencies between 395nm and 830nm. Long pass filters are essential within these instruments where short wavelength light can often dominate the signal. In instances where an excitation light source is used (for example, fluorescence spectroscopy and microscopy), the excitation light is of a shorter wavelength than the emitted signal and is, in addition, many orders of magnitude more intense. Without effective long-pass filters the measured signal would be swamped by the incident light, and accurate measurements would be impossible.

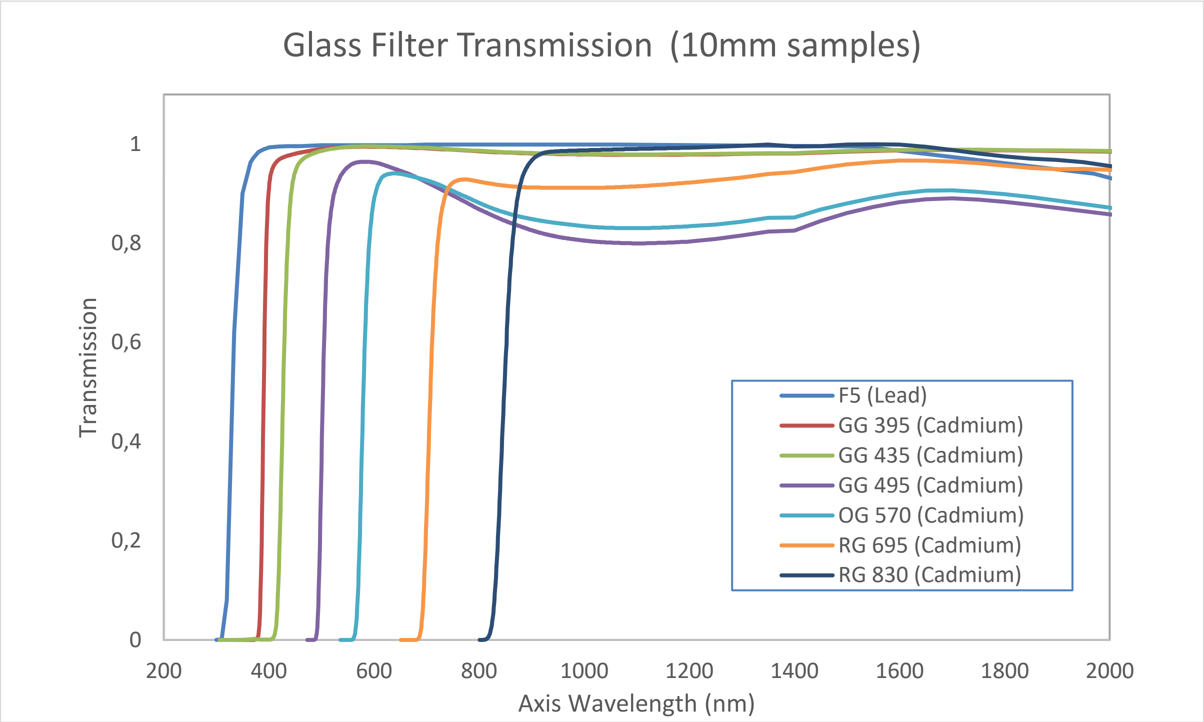


Figure 3. Light transmission from the UV to visible to NIR for F5 (lead) and a series of cadmium glasses. By varying the Cd glass composition, the filter cut-off frequency can be tailored to the specific requirements. A flat transmission curve above the cut-off frequency is advantageous for full spectrum analysis.

(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 A.

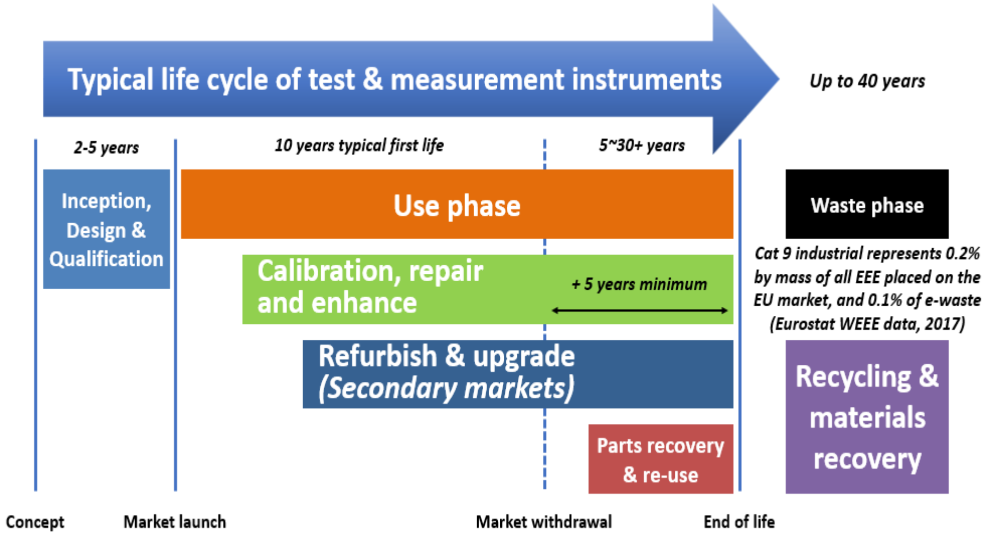
---

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:

- [x] Article is collected and sent without dismantling for recycling
- [x] Article is collected and completely refurbished for reuse
- [ ] Article is collected and dismantled:
  - [ ] The following parts are refurbished for use as spare parts: _____
  - [ ] The following parts are subsequently recycled: _____
- [ ] Article cannot be recycled and is therefore:

☐ Sent for energy return
☐ Landfilled

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

No detailed data available.

☐ In articles which are refurbished ______
☐ In articles which are recycled ______
☐ In articles which are sent for energy return ______
☐ In articles which are landfilled ______

---

6. Analysis of possible alternative substances

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

The glass used in the optical filters are made by specialist glass companies. Optical elements made from this glass are designed and manufactured (often as custom items) for companies producing industrial control and measurement products. The Test & Measurement Coalition are not aware of any substitute glass such that an alternative product without lead or cadmium could be used to manufacture filters with the same optical properties. The products outlined above are used throughout chemistry, life sciences, environmental monitoring, and other essential industries including hospitals and clinics and manufacturing process monitoring. It is essential for the functioning of these sectors that they are able to use the most sensitive and accurate instrumentation available.

Since the introduction of RoHS 1, and the restriction of the use of lead and cadmium, there has been a dramatic improvement in the development of lead- and cadmium-free glass. These glasses are used where appropriate. Glass with lead and cadmium is only used where their optical properties are required, and where no suitable alternative is available. The TMC members anticipate that the use of these glasses will continue to reduce, however, the participating companies do not foresee a removal of the need of Pb and Cd containing glass from the specialist industrial applications. Eliminating the use of lead and cadmium-glass for optical applications is not possible without the removal of some instrumentation from the EU market, and a reduction of the performance of instrumentation.

There are three main alternative types of optical filters that are used for some applications identified by Spectaris. These alternatives, however, cannot replace cadmium-based optical filter glass where the essential characteristics of cadmium filters are required. These alternatives are: alternative additives in glass; coatings on glass; and coloured “plastic fibres.” The characteristics of these alternatives and their technical performance are discussed below.

Cadmium

Alternative additives to the glass. Various other elements are added to cadmium to make a material that contains microparticles of cadmium as mixed sulphide, selenide, and telluride. The cut-off wavelength is controlled by the ratio of these elements and by their heat treatment conditions. The exact form of the cadmium compound is unclear but can be seen as very small particles in a colourless matrix. To obtain the same optical properties, alternative inorganic compounds would be needed that are thermally stable at the melting temperature of the types of glass used and gives the same optical spectrum with sharp wavelength cut-offs. Research has been conducted for decades to search for alternatives to cadmium, but with no success. The range of elements and their components that are suitable is perceived to be very finite:

- The additive must be a compound with two or more elements which must be at least one metal and match the performance of cadmium, and also at least one non-metal.
- The compound must be coloured. No other transition and rare earth metals give the same optical characteristics as cadmium.
- Halides are unsuitable as they are either water soluble or too unstable.
- Very few of the compounds that can be used as coloured glass additives are yellow, orange or bright red with sharp wavelength cut-offs.

Metal ion coloured glass, for example, is an alternative type of coloured glass filter. This alternative, however, has different shaped spectra to cadmium-based glass with lower % light transmission at longer wavelengths. Colloidal dispersions, in addition, do not give sharp wavelength cut-offs and are therefore not suitable alternatives to cadmium compounds.

Thin film coatings on transparent substrates. Interference filters (or, equivalently, dichroic filters) are widely used for certain applications but their properties are very different to glass filters based on cadmium compounds. Their main characteristic is that they absorb light within a specific but rather narrow wavelength range with sharp cut-offs at both ends of this wavelength range. Spectra of light that has passed through this type of filter are quite different to spectra obtained with cadmium glass filters. Interference filters also depend on the viewing angle and can give “ghost images.” These filters may also transmit light in unwanted side-bands at lower intensities. The light spectrum transmitted through a cadmium-based optical filter will always be the same, whereas spectra of light transmitted through dichroic filters varies according to the angle of incidence.

Transparent plastics with organic pigments. These are used as optical filters and have advantages and disadvantages; these disadvantages, however, make them unsuitable for many applications. The addition of organic dyes and organic pigments to molten glass is impossible as all are thermally unstable at glass melting temperatures. Only heat stable inorganic compounds such as cadmium chalcogenides can be used. Achieving optical clarity is not possible for all combinations of coloured compounds and polymers. Most polymers are available only as opaque materials and most pigments will not dissolve so give opaque dispersions. The main disadvantages of coloured transparent plastics are: plastics are easily scratched; they are affected by humidity as all plastics absorb water from humid air; they are affected by high temperatures (distort, degrade, change colour); organic pigments fade when exposed to ultraviolet light and polymers are also affected causing changes in colour (brittle fracture may also occur when exposed to ultraviolet light); image quality tends to be poor as the surfaces of plastic filters are easily warped, so are not optically flat; some polymer filters with organic pigments have relatively poor maximum transmission percentages at wavelengths of light that should pass through the filter; and some polymer filters transmit light at wavelengths where light needs to be blocked.

Lead

Only one type of filter glass is currently produced that contains lead and it is used because of its unique combination of properties. The interaction between the coloured metal ions and lead atoms in a glass matrix is what gives the required performance of lead-based applications. Research has not identified an alternative material with the same combination of essential properties. Glass filter manufacturers have evaluated many other combinations of ions in lead-free glass, but none give the required properties.

(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.

Most of the alternatives to cadmium and lead in filter glasses do not exhibit the required sharp wavelength “cut-offs.” Interference filters can sometimes be used as they do have sharp “cut-offs” but the wavelength at which this occurs depends on the viewing angle and so these filters are unsuitable for many applications. Most of the apparent alternatives are, in addition, detrimentally affected by harsh environmental conditions such as moisture, heat, and UV light which makes them unsuitable for many applications.

Research has been carried out for decades and alternatives to lead and cadmium have already been used where these are suitable. So far, alternatives have not been developed for the applications described in this exemption renewal request and other applications that require cadmium and lead filter glass. It is also not possible to envisage alternative designs of equipment that would provide the same function and performance without these filters; research timelines can accordingly not be estimated. No substitutes are therefore likely to be developed in the foreseeable future and by extension in the validity period required for this exemption.

The argumentation presented by the Test & Measurement Coalition in this renewal application is quintessentially already acknowledge by the Commission’s external consultants (Öko-Institut), who assessed the previously submitted application dossiers of other business and industry stakeholders. The report states that in “light of the lack of sufficient alternatives to allow for substitution or elimination of the need for cadmium and/or lead in filter glasses and in the glaze of reflectance standards for the full product range, an exemption would be justified in line with the Article 5(1)(a) criteria.”

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

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

There are currently no suitable cadmium and lead-free alternatives that meet RoHS exemption criteria on the EU market for test & measurement industrial type products and that re-designing of the test & measurement equipment could take four to five years per product line.

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 companies but sourced from third party suppliers (and so forth, potentially many levels down). Implementation of change necessitated by regulatory pressures typically starts with raw material manufacturers and the end-product manufacturers (e.g., Test and Measurement suppliers) who have the largest economic stake. Intermediate manufacturers are geographically and jurisdictionally diverse and are often SMEs. As such, this part of the supply chain is slower and more inconsistently able to adapt. Assuring full adaption in the supply chain and validating the alternatives in the final product application can and often does require up to 4 years. The general process involves communicating with the supply chain, evaluating samples, conducting design impact studies, reconfiguring the instrument and its software where necessary and testing in manufacture and validating the final assembly.

The companies reported that the validation period alone would take a minimum of 6 months and up to a year after the delivery of suitable alternatives per product. It is significant to note that this validation period would only apply if the component were a fit, form, and function drop-in replacement. If any design changes to the exemption-free part of the product would be required to accommodate for the alternative, 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. As described above, optical parts by their nature are not of low complexity. The parts can be divided into medium and high complexity:

- **Medium complexity** optical parts are where a like-for-like replacement can be substituted, and the part performs a relatively simple optical function. Despite this, the change in the optical parameters will require testing and performance validation. The average time to switch a medium complexity part for production is reported to range from 6 to 12 months.
- **High complexity** parts are optical components that perform a complex function, or are part of an optical subassembly. These parts will be critical to the performance and accuracy of the device and will require extensive characterisation, as the first step of the replacement process. The output of the characterisation will likely impact other parts of the instrument (for example, the analysis/interpretation software). Once fully characterised, these high complexity optical parts will then require testing and validation performing their function in the instrument. Depending on the application, updated documentation of the device may require notification to the appropriate competent authorities or regulatory bodies. The average time that it would take to perform a for high complexity component change for production is between 2 and 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 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

[1] www.eppa.com

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 therefore gathers technical and economic information to describe ex-ante in both qualitative and (if feasible) quantitative 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 total impact of a non-renewal is monetized in the range of 1 billion EUR to 1.5 billion EUR (conservative estimates in net losses; potential gains for suppliers of other components have been already taken into account), consisting of: economic impacts (EBIT loss) on test and measurement industrial type products' manufacturers; substitution costs and social impacts (i.e., unemployment in the EU-27).

9. Other relevant information

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

See Socio-Economic Analysis report attached.

---

10. Information that should be regarded as proprietary

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

_____

---

[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 ; 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