Exemption Request Form

Date of submission: 15 January 2020

1. Name and contact details

1) Name and contact details of applicant:

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This exemption application is submitted with the endorsement of the business associations listed below:

Japan Analytical Instruments Manufacturers' Association (JAIMA)	Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA)	The Japan Federation of Medical Devices Associations (JFMDA)
Japan Measuring Instruments Federation (JMIF)		

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 AnnexⅣ

☐ 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: Annex IV-1c

Proposed or existing wording:

Existing wording Lead, cadmium and mercury in infrared detectors.

Duration where applicable:

Category 8 for in-vitro diagnosis medical devices: July 21, 2023 to July 20, 2030

Non Industrial Category 9 : July 21, 2021 to July 20, 2028

Category 9 for industrial instrument: July 21 2024 to July 20, 2031

☐ Other: _____

3. Summary of the exemption request / revocation request

We request extension of exemption 1c for lead, cadmium and mercury contained in infrared detectors used in medical devices and monitoring /controlling instruments.

Infrared (IR) analysis and measuring instruments provide a rapid, accurate analysis of materials to provide information on the chemical composition, surface properties and spatial distribution of substances. The technology is utilised by a wide variety of industry sectors, researchers and for educational purposes, examples of which are given in this exemption request.

The choice of semiconductors intrinsically affects the infrared range detectable and usefulness of the signal produced. The current infrared detectors have features such as higher sensitivity and wider measurement wavelength ranges than their substitutes; as such substitutions are not capable to fulfil the requirements of analysis and measuring instruments.

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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:

With this application form, we ask for an extended exemption for infrared detectors used in medical devices and analytical and measuring instruments using mercury (MCT), lead sulphide (PbS), lead selenide (PbSe) and Lead zirconate titanate (PZT).

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: Not Applicable

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, cadmium and mercury for detecting infrared radiation.

4. Content of substance in homogeneous material (%weight):
   There are the following examples, depending on the type of infrared detector and its components.
   Lead: 89%(PbS)
   72%(PbSe)
   65-70%(PZT)
   Mercury: 51%(MCT)
   Cadmium: 7%(MCT)

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

   The amount of regulated substances entering into the EU
   Cadmium – 42.35g of FTIR estimated according to the report published by Strategic Directions International[1], and 0.2g of the other analysis and measuring instruments entering into EU from JBCE member companies per year.
   Mercury – 0.847g of FTIR estimated according to the report published by Strategic Directions International[2], and 0.005g of the other analysis and measuring instruments entering into EU from JBCE member companies per year.
   Lead – 0.032g of spectrophotometer estimated according to the report published by Strategic Directions International[3], and 285g of the other analysis and measuring instruments entering into EU from JBCE member companies per year.

   Please supply information and calculations to support stated figure.
   The amount of the regulated substances per one device:
   MCT: Mercury 0.1 mg or less to 1mg, Cadmium: 0.01 mg or less to 50mg,
   PbSe : Lead: 0.1mg or less
   PbS: Lead: 0.1mg or less
   PZT: Lead: 40mg or less

   Regulated substances in FTIR and spectrophotometers are estimated according to the report published by Strategic Directions International.[4]

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[1] Strategic Directions International, *The 2019 Global Assessment Report: The Analytical and Life Science Instrumentation Industry, 2019*

[2] Ibid.

[3] Ibid.

[4] Ibid.

Mercury: 0.847g = The maximum value of the device (1mg) ×the number of putting on the market of FTIR (847)

Cadmium: 42.35g = The maximum value of the device (50mg) × the number of putting on the market of FTIR (847)

Lead: 0.032g = The maximum value of the device (0.1mg) ×the number of putting on the market of spectrophotometer (326),

The other analysis and measuring instruments:

The amount of mercury, cadmium and lead not included the statistics above is available as confidential information if requested.

6. Name of material/component:

Quantum type infrared detector containing lead, mercury, and cadmium compounds. Thermal type infrared detector containing lead compounds.

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?

Analytical and measuring instruments are designed to analyse and measure qualitative and quantitative aspects of the compositions, properties, structures, and states of substances. Qualitative and quantitative information of substances is the basis of today’s science and technology, and its applications are expanding the categories (fields) including living environments, global environments, medical and health care, space exploration and the others. Frequently, often only minute quantities of material are available for analysis and so very high sensitivity is essential.

The applications in which infrared light (>~0.8µm to >20µm) detectors are used are as follows, however the list is not exhaustive:

- Use in laboratories: The instruments such as spectrometers are places in laboratories and utilized for the research, quality control over processes such as feedstock quality, forensic science and others. Examples of spectrometer applications include the identification and characterisation of unknown materials, monitoring of automotive or smokestack emissions, kinetic studies and analysis of materials with low concentrations etc.

- Use for analysis and measurement in the process / for instant and on-site analysis and measurement: Analysis and measurement in the process is that the instruments are installed and fixed, and analyses and measures in continuous (or continual) operation. Instant and on-site analysis and measurement is required for portable and mobile instruments, and are used in factories to warn workers of hazardous substances, etc. and may also be used outdoors.

- Use for environment (pollution) analysis: The instruments are utilized for environment (pollution) analysis.

- Use for workplace control and security: The instruments for workplace control are utilized for controlling and monitoring working environment including factories, workplaces, and offices. The instruments for security are utilized for monitoring leaks of flammable and toxic substances from industrial facilities.

- Use for the clinical and testing instruments and the systems: The instruments are utilized for in vitro diagnostics for blood, urine and the others, and for some in vivo diagnostics.

- Use for biotechnology: The instruments are utilized for the fields of biotechnology and for applications such as pharmaceutical research

- Use for the food industry: The instruments are utilized for analysis of ingredients and hazard analysis including foods, beverages and others.[5]

An infrared detector is a device that receives infrared rays emitted from an object and converts them into electrical signals. By measuring light emission in the infrared region, it is possible to obtain infrared spectra to determine the temperature of the object or other aspects such as the composition which is determined by the wavenumber characteristics of absorption and reflection of a material. Infrared detectors are classified into thermal type detectors or quantum type detectors.

The quantum type detectors measure the electron energy changes generated by the incident infrared rays (photons) as electrical signals, to detect the infrared intensity of the objects. Quantum type detectors are classified into intrinsic type detectors and extrinsic type detectors. The extrinsic type detectors use the same detection method as the intrinsic type detectors, but detect infrared rays using changes in energy difference generated by mixing impurities into the material.

The thermal type detectors convert the temperature changes generated by absorbing the infrared rays radiated from the objects into electric signals, to detect the intensity of the infrared rays radiated from the objects. For examples of different types of detectors refer to Figure 1.

[5] Japan Analytical Instruments Manufacturers' Association (JAIMA), *分析機器の手引き*, 2016 p.3 Excerpted,revised and translated by JBCE
https://www.jaima.or.jp/resource/jp/tebiki/pdf/tebiki2016.pdf#page=1

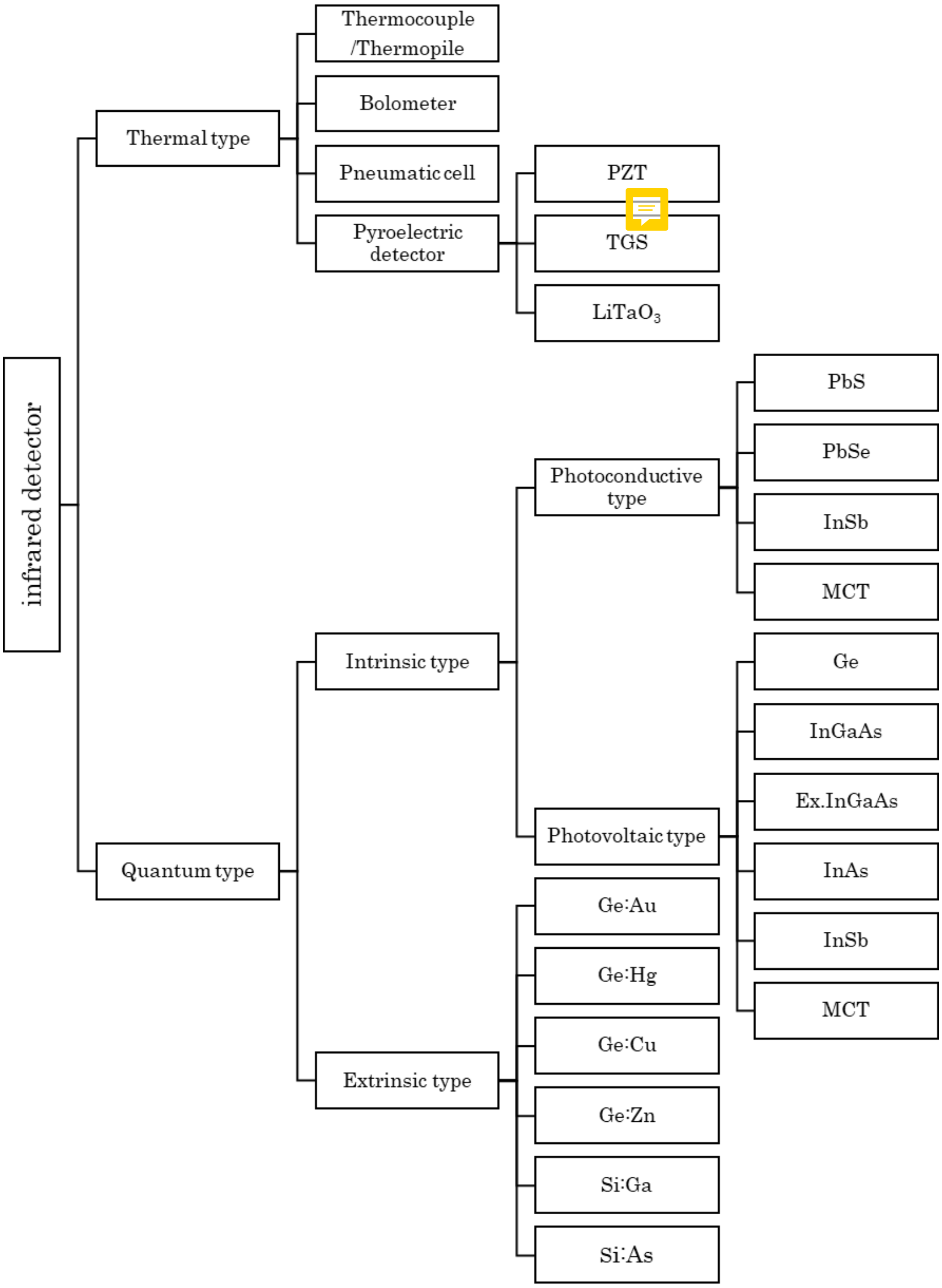

Figure 1. Classification of infrared detectors
Source: Technical Information / Infrared detectors (Hamamatsu Photonics K.K.)

<Examples of infrared detectors which contain regulated substances>

Regulated substances in detectors are listed below and not exhaustive. The quantum type detectors are Mercury Cadmium Telluride (MCT), Lead Sulfide (PbS) and Lead Selenide (PbSe).

Mercury cadmium telluride (MCT) photoconductive detectors incorporate MCT containing mercury and cadmium:
Mercury cadmium telluride is used for 2 types of detector; photoconductive detector and photovoltaic detectors in applications such as substance analysis (e.g. spectrometers such as Fourier-transform infrared spectroscopy (FTIR)), thermal imaging and gas analysers. The composition ratios of mercury telluride and cadmium telluride decide the bandgap energy values of the semiconductor, and therefore the detectable wavelength, resulting in one of the widest detection ranges of detectors for the infrared range currently available. Composition ratios determine the peak sensitivities of wavelengths from mid-infrared. Mercury cadmium telluride crystal is the only currently identified substance which enables the detection of a wide range of wavelength with appropriate sensitivity. For a comparison of sensitivity of types of detector, see Figure 2 and Table 1.

The PbS photoconductive element exhibits a photoconductive effect in which its resistance is reduced by the infrared rays received. The PbS photoconductive element is sensitive to infrared light in the range of near infrared to short-wavelength infrared which is particular to PbS photoconductive element, and has excellent characteristics such as high detection sensitivity and has stable operation at room temperature compared to other sensors in the near infrared to short-wavelength infrared wavelength region. Examples of its use include industries of steel manufacturing, mining and oil refinery.

The PbSe photoconductive detector operates due to the photoelectric effect, with resistance changing when infrared light is incident, lead selenide is uniquely able to detect the infrared light. The PbSe photoconductive detector are sensitive in the short wavelength region from near infrared to mid infrared. At the same operating temperature, the S / N ratio in the vicinity of 4μm is superior to other detectors, and its detectivity if greater than 10^{10} enabling high-precision measurements.

Thermal type detectors is Lead zirconate titanate (PZT).

There is a pyroelectric detector with Lead zirconate titanate (PZT) used as thermal infrared detectors that contains lead. Pyroelectric detectors are thermal detectors which use the pyroelectric effect (the change of internal polarisation) to detect incident infrared radiation on a material due to small changes in temperature. Some ceramic materials provide particular properties, such as, dielectric, piezoelectric, pyroelectric, ferroelectric, semiconductor, magnetic, for a wide use range including temperature. Ceramic materials which contains PZT have high pyroelectricity to temperature.

If the temperature is changed on the absorption of infrared radiation, PZT, which is electronic ceramic and has specific structure, in the detector causes the change of the voltage.

<Examples of finished products>

Examples of products using such infrared detectors are as follows.

The products incorporated in quantum type detectors are listed and not exhaustive;

・ FTIR (Fourier Transform Infrared) spectrometers

This device splits the infrared light emitted from the light source into two light paths by using a special mirror called a beam splitter that transmits / reflects half of the light. The reflected light travels to the moving mirror side moving at a constant speed, and the transmitted light travels to the fixed mirror side. The light reflected by the moving mirror and the fixed mirror is returned to the beam splitter again, and the light path difference between the beam splitter and the moving mirror and the fixed mirror changes with time, causing the light interference. The interfered light (interference wave) is detected by a detector containing mercury and cadmium (MCT), and mathematically separated into wavelength (wave number) components to obtain a spectrum. Finally, the ratio of the spectrum intensity when there is no sample to the spectrum when there is sample is used to determine the transmittance.

The speed of measurement for FTIR is of particular important as they are used in application such as kinetic studies which require the measurement of spectra up to 1000 times shorter than the overall changes in concentration, with some reactions requiring measurement of at least 10 spectra per minute.

・Radiation Thermometer

Any object will generate electromagnetic waves if the temperature of the object is above absolute zero (0K). The temperature of an object can be measured by detecting the electromagnetic waves emitted using optical sensors. As the thermal radiation (heat transfer between objects in the form of electromagnetic waves) propagates at the speed of light, radiation thermometers allow the high-speed temperature measurements to be possible. Radiation thermometers, which are non-contact measurements, can provide means for remote temperature measuring and mobile temperature measuring. As heat conduction exists in contact-type thermometers, the temperature of the measured object may be changed due to the sensor unit contacting the measured object to effect measurement accuracy. It may not be possible to contact the surface if it is moving or it is unable to be accessed if the item is in a vacuum. However, radiation thermometers can measure the temperatures of objects without changing them. Therefore, they are very useful for measuring small heat capacity objects such as films, and measuring surface temperatures such as metals.

Some radiation thermometers use an infrared detector (PbSe) that uses lead or an infrared detector (MCT) that uses mercury and cadmium. When measuring the temperature of a material that transmits visible light, but absorbs wavelengths in the specific infrared region, such as film or glass, PbSe or MCT sensitive to that wavelength is required. In addition, PbSe and MCT detectors have high sensitivity on the long wavelength side, so they can be measured accurately even when the infrared intensity is low, such as when the temperature of the measurement target is low.

・FTIR Gas Analysers (quantum type)

The infrared intensity I_0 is the value of radiation from an empty sample cell. The infrared intensity I is the value of emitted radiation from a sample in the sample cell. Both I_0 and I are detected with infrared detectors.

The absorption A is determined as "$A=-\log(I/I_0)$", which is proportional to the concentration of sample gas. The density of sample gas is calculated with the formula of absorption and density, which is proportional to the amount of detected infrared radiation.

The wide variety of gases (over 25) which can absorb infrared radiation can be measured with one MCT detector. In case of FTIR, spectra analysis enables quantitative analysis of gas composition as well as concentration. FTIR gas analyser requires the speed of response of 5 spectra per second, and MCT detectors can measure at 5 spectra per second.

・Vibrational circular dichroism spectrometer

The vibrational circular dichroism spectrometer is a dedicated instrument optimized for vibrational circular dichroism (VCD) measurement in the infrared region for molecular structure analysis of chiral molecules. VCD measurements detects differences in attenuation of left and right circularly polarized light passing through a sample. It is possible to obtain optical activity information of compounds that do not have any absorption band in the UV / VIS wavelength region such as saccharides and useful information for determining the absolute configuration of molecules. The vibrational circular dichroism signal in the infrared region is weaker by one or more orders of magnitude as compared to the electronic circular dichroism (ECD) in the UV / VIS wavelength region. Therefore, high sensitivity, high frequency responsivity and stability are required for the vibrational circular dichroism spectrometer. In the infrared region, only MCT detectors meet these requirements.

・Optical Spectrum Analyzer

This is a measuring instrument that measures and analyses the optical power corresponding to each wavelength by spectroscopy. It uses tunable optical band pass filters called monochromators using diffraction gratings. The input light is divided into narrow wavelength slots by the optical bandpass filter, then converted to electrical signals by a photodetector (O/E converter). The optical spectrum can be obtained by plotting the electrical signal while sweeping the centre wavelength of the optical bandpass filter. In the measurement of the optical spectrum in the mid-infrared region, the performance required for the photodetector is high measurement sensitivity and a wide measurement wavelength band. The MCT detector is the only detector that satisfies these requirements. The main measurement object is the optical spectrum of the light source at various mid-infrared wavelengths. Among the several light sources, for the mid-infrared laser, there is a high demand for measuring the side mode spectrum of the laser, but its output is very low compared to the peak power of the laser. Therefore, it is necessary to measure with high sensitivity.

・Spectrophotometer

Spectrophotometers use light from a light source which is separated by a diffraction grating into narrow wavelength bands used for measurement of substance composition. The light impinges incident onto a sample and passes through it with the intensity of light transmitted through the sample being detected and its intensity measured at each wavelength. The detected signal is displayed by calculating the transmittance or absorbance against wavelength. Generally, transmittance is used when measuring a solid sample, and absorbance is used when measuring a solution sample.

The UV visible near-infrared spectrophotometer measures an area of 0.2 to 3.2 micrometers with a photomultiplier tube sensitive to the ultraviolet visible region and a PbS detector sensitive to the visible and near infrared region. In a spectrophotometer that measures the near-infrared (NIR) region, a PbS photoconductive element is indispensable as a detector in order to accurately and stably measure the near-infrared wavelength range at room temperature. Potential alternatives to PbS that are sensitive in the NIR range are discussed in section 6.

・Constituent/Moisture /Thickness Meters

Wavelength is a parameter that indicates the characteristics of electromagnetic waves. Electromagnetic waves with specific wavelengths are absorbed depending on the molecular bond state of the substances irradiated it. This absorption varies with the concentration of the substances. It can measure the moisture content and thickness of substances using infrared in specific wavelength region of electromagnetic waves. The feature is that non-contact measurement. On factory production line, non-contact measurement makes it possible to measure the moisture content of products and the thickness of the coating films.

Some components / moisture / thickness meters use an infrared detector (PbSe) containing lead.

The PbSe detector has a high sensitivity not found in other detectors in a specific wavelength range, so it can accurately measure low-emissivity infrared samples such as anthracite, trace moisture, and thin films.

The products incorporated in thermal type detectors are listed and not exhaustive;

・Infrared gas/liquid analysers (thermal type)

Gases absorb infrared radiation. If the value of infrared radiation before and after absorption are measured, concentration of gas/liquid can be determined. Pyroelectric detector PZT, one of the thermal type sensors are utilized for infrared gas/liquid analysers measuring concentration of gases/liquids with the absorption of infrared radiation, as the detectivity of thermal type sensors are stable and does not change very much because of wavelengths. The gas/liquid concentration is calculated by comparison with the result of several wavelengths; therefore, quantum type (semiconductor type, photodiode and others), which has variable detectivity dependent on wavelengths, is not suitable for infrared gas/liquids analysers for analysing and measuring concentration of gases/liquids by the absorption of infrared radiation.

<Infrared detectors which have the wavelength range and sensitivity required for the function of the products mentioned above are chosen>

<u>MCT</u>

There are MCT as quantum infrared detectors containing mercury and cadmium. MCT detectors are very useful for measurement and analysis in the mid-infrared region due to their characteristics.

In the wavebands defined as the spectrographic mid-infrared, the spectral intensities are correlated to the molecular vibrational modes, which are very important for qualitative and quantitative analysis of materials and structural analysis.

A substance has an inherent molecular vibration based on its molecular structure. By observing the infrared spectrum that correlates with these molecular vibrational energy, qualitative information on the chemical structure and state of the substance can be obtained. In addition, since the intensity of the infrared spectrum correlates with the concentration, thickness, and temperature of the substance, these quantitative information can be obtained. Infrared spectrophotometers, gas analysers, spectrum analysers, and radiation thermometers based on the principle of interaction between such substances and infrared rays have been put into practical use.

Mid-infrared light detectors are an integral component of spectrophotometers, gas analysers, optical spectrum analyzers and radiation thermometers.

On the other hand, in the development of photodetectors, various compound semiconductor detectors have been proposed. However, they are correlated closely to the band gaps and the detection band which are unique to the detector substance.

PbS

Moreover, lead is contained in quantum detectors such as PbS detectors and PbSe detectors that are advantageous for measurement and analysis on the short wavelength side from the near infrared to the middle infrared.

PbS element is sensitive to the near-infrared characteristic peculiar to lead sulfide crystal, and has superior function in comparison with other detectors in the same wavelength region, having higher detection capability and room temperature operation. (See Section 6 for more details.)

PbSe

PbSe detector are sensitive to wavelengths from the near-infrared region to mid-infrared. As a result of the high detection capability in this wavelength range compared to other detectors, it can detect the infrared rays even if the intensity is weak. (See Section 6 for more details.)

PZT

Lead is contained in the thermal type detector (pyroelectric type) in PZT which can undertake measurement and analysis for a broad range of wavelengths. It is also able to withstand thermal shocks which it might experience during the product lifetime, as well as operate at higher temperature ranges than other detectors and therefore does not require the use of cooling technologies to be able to operate. (See Section 6 for more details.)

Pyroelectric material is electrically polarised and contains large electric field, and has the ability to generate a temporary voltage if it is heated or cooled. The change in temperature modifies the positions of the atoms within the crystal structure, which results in polarisation. If the pyroelectric material absorbs infrared light, the extent of the polarisation changes. The change of polarisation is utilised for infrared detection with pyroelectric detector.

<Temperature Control (cooling) for increasing detectivity and sensitivity>

As shown in Figure 1, there are a quantum type and a thermal type in infrared detectors. The capabilities of detectors, such as, wavelengths and detecitivities, differ from operating temperatures.

・The methods of controlling operating temperatures

There are three types of methods: one is the analysis and measurement with room temperature, which does not require cooling system; the second one is the method of using thermoelectric semiconductors (electronic cooling), and the third one is the methods of directly cooling the detector using liquid nitrogen (nitrogen cooling).

・Sensitivity

Generally, the sensitivity of the infrared detector increases as the operating temperature decreases. Therefore, with the same detector, the sensitivity of measurement and analysis is increased in the order of room temperature (300K, 298K), electronic cooling (263K, 243K), and nitrogen cooling (77K). See the Figures 2 and Table 1.

・ Wavelength range

Even with the same infrared detector, the wavelength range having sensitivity and the wavelength of the maximum sensitivity differ from the operating temperatures. Therefore, the substances that can be measured and analysed are different depending on the operating temperature. (See the Figures 2 and Table 1.)

・ Continuity of operation

As well as those operating at room temperature, the detectors of the electronic cooling can be operated continuously because the required operating temperature can be realized if electricity is supplied. The nitrogen-cooled detector requires that the inside of the container be cooled with a certain amount of liquid nitrogen. Therefore, when the amount of liquid nitrogen decreases, the accuracy of measurement and analysis deteriorates. Thus, some instruments must be shut down to add liquid nitrogen.

・Size of equipment

Since the detector operating at room temperature does not require a special device, the equipment is the smallest. Since the thermoelectric semiconductor is also very small, the size of the detector does not change significantly. Therefore, the size of the equipment is almost the same as that in the case where the detector operating at room temperature is mounted.Since a nitrogen-cooled detector needs to be cooled with filling the surroundings of the detection part with liquid nitrogen, the equipment is considerably larger than others. The operating temperature, 77K, requires cooling systems, such as, dewar and cryocooler, and the protection from the low temperature for workplace safety. Analysis and measurement with nitrogen cooling requires the component of filling liquid nitrogen and the additional space and engineering design to protect the other components and workers from the low temperature. Users of some analysis and measuring instruments incorporated with infrared detectors and nitrogen cooling handle with liquid nitrogen. If nitrogen is vaporised , nitrogen gas causes asphyxiation. The manufacturers of the instruments strive to provide the safety information, such as, user manuals.

For the above reasons, instruments‘ manufacturers select an infrared detector according to the objects to be measured, the required specifications (wavelength range, accuracy, sensitivity, response speed, detector operating temperature), and the temperature of the environment in which the equipment is installed. Therefore, available detectors are limited.

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

See 4.(B) and 6.(A)

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

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

2) Please indicate where relevant:

No closed loop system exists

3) No Information is available. Equipment that uses these detectors is disposed of in the same way as all types of category 8 and 9 equipment.

☐ 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: _____
  ☐ The following parts are subsequently recycled: _____
☐ Article cannot be recycled and is therefore:
  ☐ Sent for energy return
  ☐ Landfilled

4) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum: No 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

No alternative substance in infrared detectors that satisfies all of the essential performance criteria has been found yet. The detectors containing regulated substances and their possible alternative substances are described below and not exhaustive;

<u>MCT</u>

To realize practical high sensitivity and high-speed time response in the mid-infrared band, the group II-VI compound semiconductors with a band gap corresponding to direct transition in the mid-infrared band have been proposed.

As group II elements, Zn, Cd, Hg and Cn are known. Cn is a synthetic element and is not a realistic choice. Zn compounds such as ZnS and ZnSe are not applied as useful detectors as they are infrared transmitting materials. These materials are transparent to infrared radiation and are used to make windows and lenses that freely allow infrared to pass so they cannot be used as detectors. However, CdTe and HgTe are very useful as high sensitivity detectors in the mid-infrared region and the sensitivity can be controlled arbitrarily, by changing the composition ratio of CdTe and HgTe of the mixed crystals (in MCT). However they are similarly affected by RoHS

There are no other materials that have been found, which have similar performance.

For example, InAsSb photovoltaic detectors have been developed as a potential alternative to MCT detectors, but their wavelength band and sensitivity are significantly smaller and therefore it cannot be used as an alternative solution. InAsSb detectors have a high-speed response, however there are some applications that cannot be replaced in uses that require high sensitivity and wide wavelength range.

Currently MCT is the only semiconductor detector which is sensitive to wavelengths between 6 and 20μm (the upper limit of InAsSb is about 11 μm) , as outlined in Figure 2 below. This region is particularly important for substance identification where the “fingerprint” region (8-15μm) of samples are compared to a library of infrared spectra.

InAsSb demonstrates low sensitivity and noise in the lower limit of detectivity even with thermoelectric cooling. InAsSb would require liquid nitrogen cooling, which is impossible for some applications due to the size of detector module including a dewar and the structure is significantly different to conventional detectors so could not be used in like for like replacements.

In some spectral measurements of the mid-infrared laser, some weak signals like the spontaneous emission need to be measured clearly. InAsSb detectors need to be cooled down to 77K (-196 degree C) by the dewar with the liquid nitrogen or by cryocooler in order to realize the essential detectivity.

<u>PbS and PbSe</u>

Alternatives to PbS photoconductive devices that satisfy the bandwidth and sensitivity at the same temperature conditions have not been found so far (see Figure 2). InAs photovoltaic devices and InGaAs PIN photodiodes have been proposed as candidates.

InAs has the same wavelength range, with high infrared detection sensitivity only at low temperatures. It also has a high response speed. On the other hand, since the signal to noise ratio (S/N ratio) which is a measure of the useful signal produced, decreases at room temperature, this device cannot measure light accurately and cannot obtain the same sensitivity as PbS. Although the sensitivity is improved by cooling, large-scale equipment using liquid nitrogen is required to obtain the same sensitivity as the thermoelectrically cooled PbS. The additional equipment cannot be accommodated in all applications due to limitations on space, such as automatic facilities for continuous liquid nitrogen supply. Although cooling by liquid nitrogen is expected to improve the performance, there is also a concern about adverse effects on the optical system such as dew condensation, which would block infrared light due to the incorporation of a cooling device.

InGaAs, offers higher sensitivity and S/N ratio, however it cannot provide the desired measurable wavelength range as PbS or PbSe due to limitations in the substances inherent properties.

In addition, there is InAsSb as an alternative to PbSe, which is sensitive to long wavelengths, but cannot provide the same signal-to-noise ratio as PbSe.

PZT

A potential alternative to PZT pyroelectric detectors are thermopile detectors which has equivalent sensitivity. However, disturbance noises such as the temperature changes in surroundings, results in smaller S/N ratio and lower accuracy of measurement results with thermopile detectors. The accuracy achieved using thermopiles is not enough for applications such as infrared gas analysers.

Other potential lead-free pyroelectric substitutes include Lithium tantalate, Strontium Barium Niobates (SBN) and TGS (glycine trisulfide). Lithium tantalate is highly stable single crystal material however it has a sensitivity of only half of that of PZT and a reduced S/N ratio and therefore cannot replace PZT sensors. The improvement of sensitivity is currently being studied.

SBN (strontium barium niobate) has 1.2 times sensitivity of PZT, but stable measurement is not possible because the pyroelectric coefficient is reduced by thermal cycling, resulting in the decrease of detectivity of gas/liquid analysis. TGS (glycine trisulfide) has high sensitivity but is deliquescent (so change in quality in air) and has low curie temperature which is 69 degrees Celsius in comparison with 287 degree Celsius of PZT when in use and therefore is not suitable for infrared gas/liquid analysers. If the Curie temperature is exceeded, the detector will stop working. Exposure to infrared is likely to heat the detector and could exceed 69 degrees. Other ferroelectric materials have been studied over the world. However, the stability and sensitivity of PZT has not been replaced by those of other materials as they do not offer the same performance or properties.

PZT has high level sensitivity for the wide wavelength range from near infrared to mid infrared. PZT can be utilized for analysis of a wide variety of gases/liquids. Any other sensors apart from PZT cannot be used for such a wide variety of gases/liquids.

Japan Business Council in Europe

As described above, infrared detectors using lead, mercury and cadmium have the features of no alternative technologies currently available.

Because they have high sensitivity in specific wavelength regions, the high-precision analysis and measurement of substances with characteristics, such as infrared transmission, absorption and reflection at a certain wavelength becomes possible. Therefore, the production and research and development of products containing such substances are necessary technologies.

Also, high-performance analysis and measuring instruments with high sensitivity are used in the field of university and commercial research and development, and are supporting the development of science and technology.

Furthermore, since it is possible to capture weak infrared energy by the use of RoHS regulated substances, due to the high detectivity and sensitivity in the required wavelength ranges, it is possible to analyse and measure composition of minute samples. For example, it has helped to tackle problems such as analysis of micro-plastics, which has become an environmental problem in recent years. For this reason, infrared detectors containing lead, mercury and cadmium will continue to be necessary technologies for protecting human health and the environment, due to their wavelength characteristics and high sensitivity. The detectivity against wavelength of many types of commercially available infrared detectors are compared in Figure 2 shown below. Note that some plots are from detectors at 77K (liquid nitrogen cooled) and at 300K (room temperature, so no cooling).

Sensitivity to infrared radiation and signal to noise ratio are measured as one parameter “detectivity”. The detectivity, spectral range and operating temperature of infrared detectors are listed in the table below.

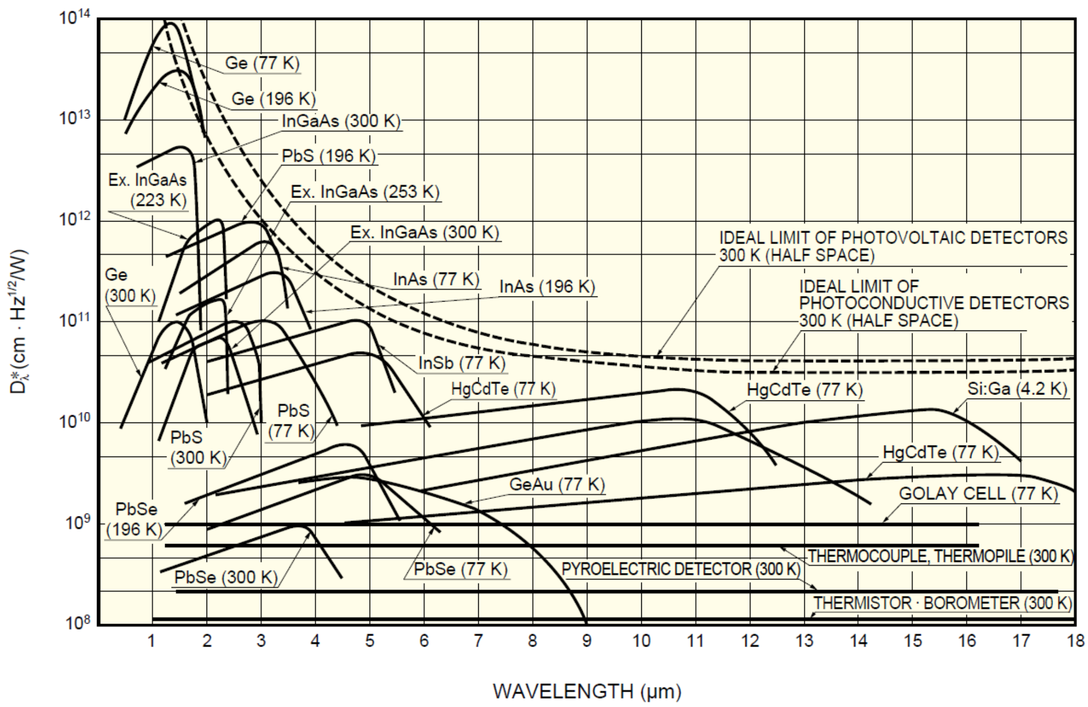

Figure 2. Spectral response characteristics of various infrared detectors
Source: Technical Information / Infrared detectors (Hamamatsu Photonics K.K.)
※Information as of September 2007

Table1 Infrared detector comparison table

	Detector	Spectral response (μm) Typ.	Operating temperature (K) / (℃) Typ.	Detectivity D* (cm・$Hz^{1/2}$ /W) Typ.
Thermal Type	**PZT,TGS,$LiTaO_3$**	1-20 [*1]	300/27	2.0×10^{8}
Quantum Type	**PbS**	1-2.8	298/25	5.0×10^{10}
	PbS	1-3.2	263/-10	1.0×10^{11}
	PbSe	1-4.8	298/25	2.5×10^{9}
	PbSe	1-5.1	263/-10	5.0×10^{9}
	MCT (PC)[*2]	1-14	77/-196	4.0×10^{10}
	MCT (PC)[*2]	1-17	77/-196	1.3×10^{10}
	MCT (PC)[*2]	1-25	77/-196	1.0×10^{10}
	MCT (PV)[*3]	1-13.5	77/-196	3.0×10^{10}
	Type-II superlattice infrared detector	?-14.3	77/-196	1.6×10^{10}
	InAsSb	2-6	243/-30	5.0×10^{9}
	InAsSb	2-5.9	77/-196	8.0×10^{10}
	InAs	1-3.5	298/25	4.0×10^{9}
	InAs	1-3.5	263/-10	1.8×10^{10}
	InGaAs	0.7-1.7	300/27	5.0×10^{12}
	Ex InGaAs	1.2-2.55	253/-20	2.0×10^{11}

*1 Thermal types have little peaks of wavelengths.

Window materials are chosen according to the wavelengths required.

*2 PC：Photoconductive detector

*3 PV：Photovoltaic detector

Source: Technical Information / Infrared detectors (Hamamatsu Photonics K.K.)

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

Reliability is not an issue and no substitution is possible.

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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.

Many types of infrared detector have been developed and those available commercially are described above in section 6 (A). There are also other types that are subject to research at a low technology readiness level but have not been commercialised as they give performance that is unsuitable as substitutes.

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

No substitutions are currently possible as described in section 6

The development of substitute detectors is on the way, but at present there are no substitutes with satisfactory characteristics.

After the detector characteristics have been improved, the equipment manufacturer will conduct functional evaluations. Then the equipment manufacturer conducts a detailed performance and durability evaluation. At the same time, the system for procurement, manufacturing and service will be improved.
The ERA Technology (2006) says: "The new product development time for many Category 8 and 9 products is over 4 years and can be 7 years or longer."[6]
So, it is estimated that it will take 4-7 years to develop the equipment after the properties of the substitute detector are improved.

However, the equipment manufacturers sometimes change electronic circuits and mechanical designs in order to adopt substitute detectors, and it is not appropriate to describe the equipment manufacturer's schedule in general. In addition, a longer schedule is required if new cooling method is essential.

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[6] ERA Technology (2006) , Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, 2006 , p.29 https://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

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

Lead zirconate titanate (PZT) is an SVHC.

☒ Candidate list

Lead zirconate titanate (PZT) is an SVHC.

☐ Proposal inclusion Annex XIV

☐ Annex XIV

☐ Restriction

☐ Annex XVII

Mercury (MCT) is in the entry 18. 'Mercury compounds'. The scope is limited to preservation, textiles and yarn, treatment of industrial waters.

Cadmium (MCT) is in the entry 23. 'Cadmium and its compounds'. The scope is limited to synthetic organic polymers, paints, plating, brazing fillers, metals.

Lead (PbS, PbSe and PZT) is in the entry 63. 'Lead and its compounds'. The scope is limited to jewellery articles. The entry 63 shall not apply to articles within the scope of Directive 2011/65/EU.

☐ Registry of intentions

☒ Registration Lead zirconate titanate (PZT) is registered.

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

Name of document:

Registration dossier for PZT https://echa.europa.eu/registration-dossier/-/registered-dossier/14607

(B) Elimination/substitution:

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

☐ Yes. Consequences? _____

☒ No. Justification:

As described in this document, infrared detectors that do not use lead, cadmium or mercury cannot be substituted due to their inferior performance.

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

☐ Yes.

☐ Design changes:

☐ Other materials:

☐ Other substance:

☒ No.

Justification: See section 6.(B)

3. Give details on the reliability of substitutes (technical data + information):
Substitutions do not exist

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

1) Environmental impacts:

FTIR spectrometers utilising MCT detectors and infrared gas/liquid analysers are used in environmental monitoring in applications such as the measurement of mircroplastics in water or emissions measurement and could no longer be carried out if the exemption renewal is not granted. This would have the consequence of reducing the ability to support environmental initiatives and monitoring pollution within the EU

2) Health impacts: Some

Infrared detector instruments are utilized for in vitro diagnostics, and for some in vivo diagnostics. And the instruments incorporating MCT or PbS detector are utilized in research analysis for blood, urine and the others. If this exemption was not to be granted these applications would not be able to be supported and would have to rely on other less sensitive techniques, potentially negatively impacting the health of EU citizens.

3) Consumer safety impacts: Not Applicable

⇨ 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: Substitutions do not exist

b) Have you encountered problems with the availability? Describe: Substitutions do not exist

c) Do you consider the price of the substitute to be a problem for the availability?
No substitutes exist

☐ Yes ☒ No

d) What conditions need to be fulfilled to ensure the availability?
Development and sufficient availability of a substitute that meets all essential criteria

(D) Socio-economic impact of substitution:

Substitutions do not exist

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

☒ Increase in direct production costs

The production costs of many types of manufacturing process would be adversely affected as quality control of substances would either not be available or would have to use a less sensitive detector. Consequentially other, less suitable control measures as part of the manufacture would have to be used.

☐ Increase in fixed costs

☐ Increase in overhead

☐ Possible social impacts within the EU

☒ Possible social impacts external to the EU

There would be many negative impacts if this exemption were not to be renewed:

EU industry would become less competitive if infrared detectors were available outside of the EU but not in the EU. A large number of academic research is dependent upon the use of infrared detectors as an analysis tool for novel material developments as well as industries like pharmaceuticals. Without the exemption, there would be job losses as these roles and funding for research are transferred outside the EU.

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: Not Applicable

9. Other relevant information

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

None

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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:

The amount of regulated substances entering in EU of other analysis and measuring instruments in 4.(A). 5 is calculated with the data of exportation to EU from individual companies. Exportation data of individual companies is confidential and should be protected by laws and regulations.