Consultation Questionnaire Exemption 1(c) of RoHS Annex IV

Current wording of the exemption:

Lead, cadmium and mercury in infrared detectors

Expires on 21 July 2021 for equipment of cat. 8 and 9 other than in-vitro diagnostics and industrial monitoring and control instruments

1. Acronyms and Definitions

FTIR	Fourier transform infra-red
HgCdTe	Mercury cadmium tellurium (MCT)
JBCE	Japan Business Council in Europe
LWIR	Long wavelength infrared
MCT	Mercury cadmium tellurium
MWIR	Medium wavelength infrared
PbSe	Lead selenide
PbS	Lead sulphide
PPTF	Polish Technological Platform on Photonics
PZT	Lead zirconate titanate
IR	Infrared
S/N	Signal over noise

2. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

COCIR, JBCE, LASER COMPONENTS, PerkinElmer and PPTF have submitted requests[2] for the continuation of the above-mentioned exemption. The requests have been subject to a first completeness and plausibility check. The applicants have been re-quested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation.[3]

SUMMARY OF THE EXEMPTION REQUEST OF **JBCE**

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

[2] Exemption requests available at https://rohs.biois.eu/Ex_1c-IV_COCIR_Renewal-Request.pdf, https://rohs.biois.eu/Ex_1c-IV_JBCE_Renewal-Request.pdf, https://rohs.biois.eu/Ex_1c-IV_LC_Renewal-Request.pdf, https://rohs.biois.eu/Ex_1c-IV_PE_Renewal-Request.pdf, https://rohs.biois.eu/Ex-1c-IV_PPTF_Renewal-Request.pdf

[3] Clarification questionnaire available at https://rohs.biois.eu/Ex_1c-IV_COCIR_Questionnaire-1_Clarification.pdf, https://rohs.biois.eu/Ex_1c-IV_JBCE_Questionnaire-1_Clarification.pdf, https://rohs.biois.eu/Ex_1c-IV_LC_Questionnaire-1_Clarification.pdf, https://rohs.biois.eu/Ex_1c-IV_PerkinElmer_Questionnaire-1_Clarification.pdf, https://rohs.biois.eu/Ex_1c-IV_PPTF_Questionnaire-1_Clarification.pdf

JBCE requests the renewal of the exemption in its current scope and wording:

Lead, cadmium and mercury in infrared detectors

According to JBCE, "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."

The applicant requests a renewal of this exemption for 7 years for all equipment of cat. 8 and 9.

SUMMARY OF THE EXEMPTION REQUEST OF **COCIR** AND **LASER COMPONENTS**

COCIR and Laser Components request the renewal of the exemption with the following scope and wording:

*"**Lead in infra-red light detectors**".*

Both applicants request a renewal period of 7 years.

According to COCIR, "PbSe infrared detectors are used in medical devices called capnometers, which are used to monitor the breathing of patients in EU hospitals and clinics. PbSe is the only detector material that meets all of the essential criteria and is able to detect small changes in breathing using a capnometer that can be indicative of health conditions as well as difficulties with breathing. All potential substitutes either do not adequately respond to changes in CO_2 concentrations in patients' exhaled breath, they respond too slowly, or the detectors require cooling. Cooling requires extra bulky equipment and would cause condensation of water from exhaled air onto the detector's surface. This will freeze and the ice crystals will block infrared light and so make the detector insensitive."

According to Laser Components, "PbSe and PbS infrared detectors have unique characteristics that enable them to be used in a wide variety of applications. They are used in near infrared analysers used by very many diverse industries, medical devices for analysis of carbon dioxide in patients' breath and in spark detection systems. These detectors are used because of their high sensitivity in the near infrared range and can be used without cooling. Another advantage over thermal heat detectors is the very fast response times of the lead based detectors, which is essential in many applications."

SUMMARY OF THE EXEMPTION REQUEST OF **PPTF**

PPTF requests the renewal of the exemption with the following scope and wording:

*"**Cadmium and mercury in infra-red detectors"***

According to PPTF, "The variable band gap $Hg_{1-x}Cd_xTe$ (also called in short HgCdTe or MCT) has been undeniably the champion among the large variety of material systems, offering 2x up to 100x better detectivity levels in the MWIR (3 to 8µm) and especially LWIR (8 to 14µm) spectrum. The are possible substitutes used in less demanding measurement applications – III-V compound semiconductor detectors. However, despite many years of development there have not been yet any commercially available detectors matching MCT detectors in terms of detectivity."

The applicant requests a renewal of this exemption for 7 years.

SUMMARY OF THE EXEMPTION REQUEST OF **PERKINELMER**

PerkinElmer requests the renewal of the exemption with the following scope and wording in the clarification questionnaire:

*"**Cadmium and mercury in infra-red detectors of Fourier transform infra-red (FTIR) spectrometers and microscopes**"*

PerkinElmer claims "[…] that MCT [mercury cadmium telluride] is the only detector material currently available which is able to provide all of the following characteristics required for FTIR spectrometers and microscopes:

- *Photoconductor with an electrical resistance that decreases as the level of incident infra-red light increases;*
- *High sensitivity to small infra-red light level changes producing a strong signal;*
- *Low dielectric constant, ensuring that the signal to noise ratio is maximised;*
- *Relatively low electrical resistance when not exposed to infra-red light;*
- *Low noise, otherwise averaging methods have to be used which increases measurement time by a factor of 4 for an improvement of the signal to noise ratio of two due to a square law relationship;*
- *Ability to detect over a wide range of IR regions therefore requiring both low and high carrier concentrations; and*
- *FTIR spectrometers for kinetics studies must have very fast response to changes in concentration of substances with typical requirements being the ability to measure spectra in times that are 1000 times shorter than the overall changes in concentration."*

The applicant requests the renewal of this exemption for 7 years.

The stakeholder consultation is part of the review process for the request at hand. The objective of this consultation and the review process is to collect and to evaluate information and evidence according to the criteria listed in Art. 5(1)(a) of Directive 2011/65/EU.[4]

To contribute to this stakeholder consultation, please answer the questions below by December 2nd, 2020.

3. Questions

1. The applicants have requested the renewal of exemption 1(c) of RoHS Annex IV with partially different scopes and wording.
   a. Please let us know whether you support or disagree with any of the above wordings, scopes and requested durations of the exemption. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a).
   b. If applicable, please suggest an alternative wording and duration and explain your proposal.
2. Please provide information concerning possible substitutes or elimination possibilities at present or in the future so that the requested exemption could be restricted or revoked. Please specify which of the requested exemption scopes and wordings you address in your answers.
   a. Please explain substitution and elimination possibilities and for which part of the applications in the scope of the requested exemption they are relevant.
   b. Please provide information as to research to find alternatives that do not rely on the exemption under review (substitution or elimination), and which may cover part or all of the applications in the scope of the exemption request.
   c. Please provide a roadmap of such on-going substitution/elimination and research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.

[4] Directive 2011/65/EU (RoHS) available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

3. Do you know of other manufacturers producing devices of comparable features and performance like the ones in the scope of this exemption request that do not depend on RoHS-restricted substances, or use smaller amounts of these substances compared to the applications in the scope of this exemption?
4. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, if you have information on socioeconomic aspects, please provide details in respect of the following:
    a. What are the volumes of EEE in the scope of the requested exemptions which are placed on the market per year?
    b. What are the volumes of additional waste to be generated should the requested ex-emption not be renewed or not be renewed for the requested duration?
    c. What are estimated impacts on employment in total, in the EU and outside the EU, should the requested exemption not be renewed or be renewed for less than the re-quested time period? Please detail the main sectors in which possible impacts are expected – manufacturers of equipment in the scope of the exemption, suppliers, re-tail, users of MRI devices, etc.
    d. Please estimate additional costs associated should the requested exemption not be renewed, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).

    Please specify which of the requested exemption scopes and wordings you address in your answers.
5. Any other information you would like to share?

Please note that answers to these questions can be published in the stakeholder consultation, which is part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.

Please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that the project team can contact you in case there are questions concerning your contribution.

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1. Background

In the medical field, sensors are used for monitoring the CO2 content of the air inhaled and exhaled by patients in need of ventilation. This application is called capnography, and the sensor is used in intensive care units (in house) and in emergency care (e.g. in ambulance cars or helicopters) paired with ventilators and monitors. The device itself is rather small and light weight, features a cable to the host system (ventilator or monitor) and is plugged onto the ventilator tubing near the patient's face.

The application of capnography on ventilated patients from pediatrics to adults is state of the art in medicine. There are sidestream capnographs (using a pump and tubing to extract a gas sample for measurement) and mainstream capnographs (directly applied to the ventilator tubing). Mainstream capnographs offer the advantage of fast rise times and small delays with respect to CO2 concentration vs. time. The operation principle is a non dispersive infrared (NDIR) measurement, where the attenuation of gases (here CO2) in characteristic wavelength ranges (here around 4.3µm) is used to quantify the gas content. Infrared light is sent from a broadband (e.g. thermal) source through the sample gas to a detector, the spectrum being narrowed down by a bandpass filter. The more CO2 is present, the less light reaches the detector. A second detector and bandpass filter combination is used to correct for changes in the total light intensity present (e.g. depending on dirt in the optical path or intensity fluctuations in the source). These detectors contain a very small amount of lead (Pb) – less than 100µg.

In order to be suitable for clinical use, all medical capnographs have to fulfil tight accuracy specs in the relevant concentration range from 0 to 10 vol.% CO2. For outdoor use in emergency applications, additional requirements like a broad temperature range from -20 to +50 degrees Celsius plus robustness against shock and vibration (use in ambulance cars and helicopters) arise. This combination of requirements has been met by using PbSe detectors which cannot be substituted without loss of performance, as explained in more detail below.

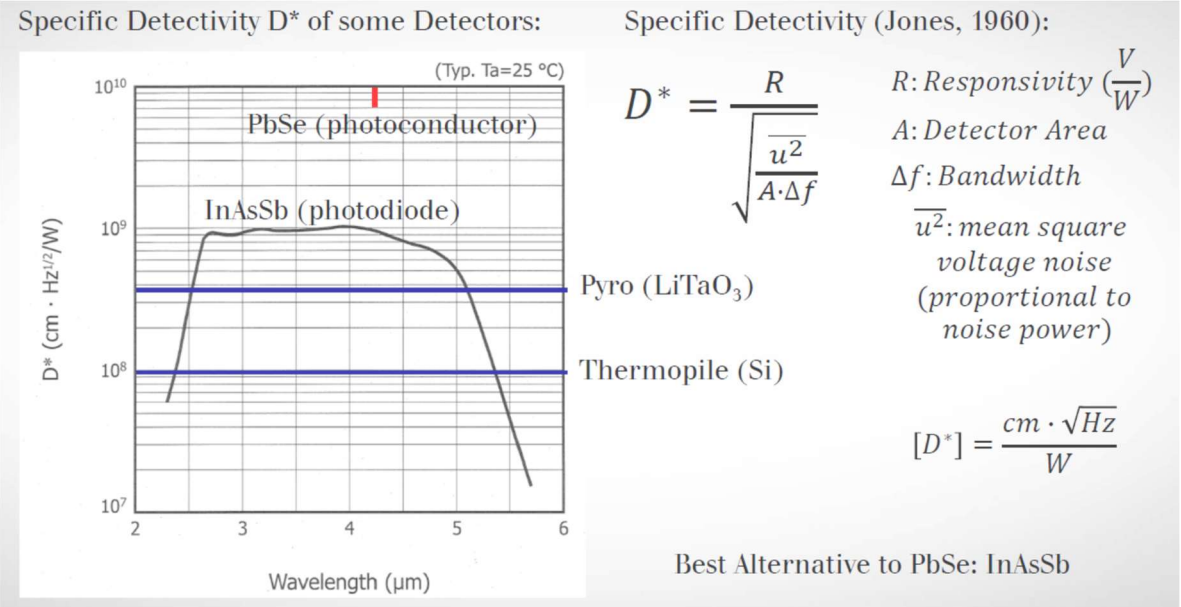
The performance of the mainstream capnograph is fine tuned to the host systems with respect to concentration accuracy, signal-to-noise ratio and rise time. For the clinician, it is important to see exactly how much CO2 is present during inhalation and exhalation and how the curves appear. From this he/she can deduce if the ventilation parameters are set correctly or if there is an issue with the air delivery and removal. A short rise time results in meaningful clinical data even for patients with high breath rates or steep breathing patterns. Longer rise times tend to suppress data that otherwise can be useful to the clinician.

The use of mainstream capnographs is state of the art and essential for supporting clinicians using ventilators and monitors worldwide on patients in intensive care units and in acute care. The non-availability of these sensors would deteriorate the quality of ventilation and consequently of medical care on patients with breathing impairments.

So we fully support the applications of COCIR and Laser Components for the field of medical mainstream capnography where PbSe detectors cannot be replaced without deterioration of device performance. A renewal of the exemption for another 7 years would be appreciated.

2. Alternative Detectors for Medical Mainstream Capnography

This CO2 sensor technology features 2 detectors with the following basic requirements: 1) Fast response time and 2) High signal-to-noise ratio (S/N) around 4.3µm. These requirements have been fulfilled in the design of the sensor by using lead selenide (PbSe) photoresistors of 2x2mm2 sensitive area. In recent years, we have been searching for alternative detector materials, the graph attached shows a comparison of the relevant figure of merit which is the specific detectivity D*.



The alternatives to PbSe photoresistive detectors are thermal pyroelectrical detectors, thermal thermopile detectors and InAsSb photodiode detectors. It can clearly be seen that PbSe is technically superior to the known alternative materials (detectivity D* almost an order of magnitude higher). So a 1:1 substitution of PbSe with another material yielding the same performance is to our present knowledge not possible.

3. Mainstream Capnography Devices from other Manufacturers

To our knowledge some other sensor manufacturers apply the alternative detector technologies shown in the graph above: Whereas thermopiles do not seem to be implemented (because of their very poor performance in terms of D*), both pyroelectrical detectors and InAsSb can be found. Pyroelectrical detectors suffer from microphony, yielding signal artefacts when subjected to vibration and shocks. This is not acceptable in emergency medicine (e.g. on board of helicopters or ambulance cars). Both alternative technologies require longer integration (i.e. averaging) times than PbSe in order to achieve acceptable signal-to-noise ratios, so the capnograms (curves of CO2 concentration vs. time) are more blurred and contain less useful information for the clinician. With this kind of low end capnography device, it is still possible to derive an end tidal (i.e. end exspiratory or end inspiratory) CO2 concentration but not a high quality capnogram. This is the more the case, the higher the respiration rates, i.e. the smaller the patient. So using the alternative materials

clearly results in a deteriorated performance ultimately leading to lower quality clinical information than what is current state of the art.

4. Ecological and Socio-Economic Aspects

The annual sales figures of our medical mainstream capnographs sum up to an emission of lead of less than 1g into the environment. This very low amount ought to be weighed against the additional medical benefit that state of the art PbSe based devices offer over existing lead-free alternatives (see above).

In order to come up with a lead-free detector technology that would allow for a 1:1 replacement of PbSe, a basic research program would have to be set up. The goal would be an uncooled detector device with a D* comparable to PbSe around 4.3µm with a small form factor (i.e. small TO can or even SMD), a sensitive area on the order of 1mm2 and a price range on the order of EUR 10,- or less.

The subsequent development and medical certification of a mainstream capnography device would bind considerable R&D resources over 3-4 years and cost several millions of Euros.

Summary

So in summary we fully support the applications of COCIR and Laser Components for the field of medical mainstream capnography where PbSe detectors cannot be replaced without deterioration of device performance. A renewal of the exemption for another 7 years would be appreciated.

Lübeck 2020-11-11 Bernd-M. Dicks