Consultation Questionnaire Exemption 1 of RoHS Annex IV

Current wording of the exemption:

Lead, cadmium and mercury in detectors for ionising radiation

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

# Acronyms and Definitions

JBCE Japan Business Council in Europe

CdTe Cadmium Tellurium

CdZnTe Cadmium Zinc Tellurium

# Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[[1]](#footnote-2) 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 and JBCE submitted requests[[2]](#footnote-3) for the renewal of the above-mentioned exemption. The request has been subject to a first completeness and plausibility check. The applicant has been re-quested to answer additional questions and to provide additional information, available on the request webpage of the stakeholder consultation.[[3]](#footnote-4)

SUMMARY OF THE EXEMPTION REQUESTS

JBCE requests the renewal of the exemption for cadmium only (c.f. question 1 below).

According to JBCE, *“By the transmission ability, X-rays and gamma rays are utilized to see inside the human body or objects in the field of medical diagnostics, non-destructive testing, food inspection, baggage screening and so on. For these applications, the following 4 technical requirements are crucial for the radiation detectors.*

*- High sensitivity*

*Higher sensitivity of the detector enables reduction of radiation dose, leading to lower risk of the patient, medical staff and operators. This is critical for the citizen’s human health.*

*- High spatial resolution*

*High spatial resolution is an ability to see the fine object clearly, and this is the fundamental function of the “imaging detector” to find the small pathological change of the patient, abnormality of the object, contaminations of the foreign substance, explosives in the baggage and so on.*

*- High energy resolution*

*The energy information of the radiation can give the new additional functions to the radiation imaging. It is used not only for removing the scattering ray to improve the image quality, but also for material discrimination ability by the multi-energy imaging.*

*- Room temperature operation*

*If the detector cannot be operated at room temperature, it requires the cooling system and the whole device size becomes too large or the device cannot be realized. It is practically very important.*

*Cadmium telluride (hereafter CdTe) or cadmium zinc telluride (hereafter CZT) detector meets the above 4 technical requirements and used for category 8 and 9 applications, contributing to the society, such as human health, safety of the plant, reliability of the products, security at the border and so on.*

*The above 4 technical requirements should be considered to search for the alternative detector of CdTe and CZT.*

*An indirect conversion type detector using the scintillator has lower spatial resolution due to the spreading of the scintillation light in principle. Therefore, the alternative of CdTe or CZT is limited to the same direct conversion type using the semiconductor material.*

*So far only a few semiconductor materials, such as silicon (Si), amorphous selenium (a-Se), germanium (Ge), CdTe and CZT have been used as the direct conversion type detectors and some other semiconductors are the new candidates. However, only CdTe or CZT can satisfy 4 important requirements and there are no alternatives of them so far.*

*If this exemption is expired, the medical diagnosis will become poor and the radiation exposure risk to the patient or the medical staff will increase.*

*This technology of making invisible object visible can contribute to the society very much, so depriving the society of this technology will cause a huge negative impact rather than the environmental merit. Therefore, we apply for the renewal of this exemption.*

COCIR requests the exemption renewal for lead and cadmium (c.f. question 1 below) for 7 years.

According to COCIR, the *“[…] renewal request includes uses of two of the RoHS substances in two different types of detector. One type contains cadmium and the other contains lead.*

***Cadmium***

*Cadmium telluride and cadmium zinc telluride are used in semiconductor flat panel detectors for imaging using ionising radiation. They are used for X-ray imaging as well as -radiation imaging with PET and SPECT. They have the advantage of giving superior image quality with lower radiation doses. These materials are superior overall to all other detector materials and so this exemption needs to be renewed to allow their use to continue.*

*These detectors are also used in category 9 applications because of their superior image quality and so this exemption also needs to be renewed for non-industrial monitoring and control instruments. The health advantage to patients from the use of CT and CZT in reducing the radiation dose to the patients is likely to be much more important than the very small potential of cadmium contamination at end of life.*

***Lead***

*Lead is used in ionisation chambers that are used to regulate the quantity of X-radiation that patients are exposed in EU hospitals and clinics. These chambers have been specifically designed to be used in most types of X-ray system sold in the EU and research has shown that all alternative materials and designs are either inferior or unsuitable. Alternative materials can only be used if the entire X-ray system is completely redesigned and this will take many decades before all existing systems can be replaced.*

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]](#footnote-5)

To contribute to this stakeholder consultation, please answer the questions below by November 18th, 2020.

# Questions

1. COCIR requested the renewal of the above exemption for 7 years for medical devices (cat. 8) excluding mercury:

*Cadmium and lead in detectors for ionising radiation*

JBCE excluded lead, too, from the requested exemption, which it asks to be renewed for 7 years:

*“Cadmium in detectors for ionising radiation”*

* 1. Please let us know whether you support or disagree with the wording, scope and re-quested duration of the exemption. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a).
	2. If applicable, please suggest an alternative wording and duration and explain your proposal.
1. Please provide information concerning possible substitutes or elimination possibilities at pre sent or in the future so that the requested exemption could be restricted or revoked.
	1. Please explain substitution and elimination possibilities and for which part of the ap-plications in the scope of the requested exemption they are relevant.
	2. 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.
	3. 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.
2. 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?
3. 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:
	1. What are the volumes of EEE in the scope of the requested exemptions which are placed on the market per year?
	2. 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?
	3. 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.
	4. 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).
4. Any additional information which you would like to provide?

**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.**

1. It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017 [↑](#footnote-ref-2)
2. Exemption requests available at <https://rohs.biois.eu/Ex_1-IV_COCIR%20_Renewal-Request.pdf>, <https://rohs.biois.eu/Ex_1-IV_JBCE_Renewal-Request.pdf> [↑](#footnote-ref-3)
3. Clarification questionnaires available at <https://rohs.biois.eu/Ex_1-IV_COCIR_Questionnaire-1_Clarification.pdf>, <https://rohs.biois.eu/Ex_1-IV_COCIR_Questionnaire-1_Clarification.pdf> [↑](#footnote-ref-4)
4. Directive 2011/65/EU (RoHS) available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT> [↑](#footnote-ref-5)