4. Exemption 1 of Annex IV: Pb, Cd and Hg in detectors for ionising radiation

The exact wording of the current exemption IV-1 is as follows:

"*Lead, cadmium and mercury in detectors for ionising radiation*"

The exemption expires on 21 July 2021 for EEE of category 8 other than in-vitro diagnostic medical devices (IVD) and for EEE of category 9 others than industrial monitoring and control instruments (IMCIs). For IVDs, the exemption expiry date was scheduled for 21 July 2023, and for IMCIs for 21 July 2024.

Declaration

In the sections preceding chapter "4.4 Critical review", the phrasings and wordings of applicants' and stakeholders' explanations and arguments have been adopted from the documents they provided as far as required and reasonable in the context of the evaluation at hand. Formulations were only altered or completed in cases where it was necessary to maintain the readability and comprehensibility of the text. These sections are based exclusively on information provided by applicants and stakeholders, unless otherwise stated.

Acronyms and definitions

JBCE	Japan Business Council in Europe
CdTe	Cadmium Tellurium
CdZnTe	Cadmium Zinc Tellurium
COCIR	European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
CT	Computed Tomography
PET	Positron emission tomography
SPECT	Single-photon emission computed tomography
WEEE	Waste Electrical and Electronic Equipment

4.1. Background

COCIR (2020a) and (JBCE 2020a) requested the renewal of exemption 1 of Annex IV for the maximum validity period of seven years on 2 and 6 January 2020 respectively. No other stakeholders than the applicants contributed to the online consultation.

4.1.1. History of the Exemption

Goodman, Paul (2006) assessed that this exemption would be required if EEE of category 8 was to be included into the scope of the RoHS Directive, which was not yet the case in RoHS 1 (Directive 2002/95/EC). When EEE of category 8 was included into the scope of RoHS Directive 2011/65/EU (RoHS 2), exemption 1 was listed on Annex IV when it was officially published in 2011. Applications for renewal were submitted in time, and exemption 1 will be reviewed for the first time to adapt it to scientific and technical progress.

4.1.2. Summary of renewal request by (JBCE 2020a)

The below table gives an overview of the exemption renewal requests and the requested wordings. All applicants request the renewal of exemption 1 for the maximum 7 year period for EEE categories 8 and/or 9.

Table 4-1: Overview of exemption requests

Applicant	Proposed Wording	Substances and Applications
JBCE (2020a)	*Cadmium in detectors for ionising radiation*	- Category 8 medical devices other than in-vitro diagnostic -medical devices - Cat. 9 monitoring and control instruments including monitoring and control instruments in industry.
COCIR (2020a)	*a. Cadmium in cadmium telluride and cadmium zinc telluride X-ray detectors for digital imaging* *b. Lead in coatings of ionization chambers of medical X-ray devices*	- Category 8 medical devices other than in-vitro diagnostic medical devices - Category 9 monitoring and control instruments other than monitoring and control instruments in industry

Summary of the renewal by JBCE

(JBCE 2020a) request the renewal of the exemption for category 8 medical devices other than in-vitro diagnostic medical devices and for cat. 9 monitoring and control instruments including monitoring and control instruments in industry for the maximum seven years validity period.

According to JBCE (2020a), *"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." Therefore, a detector for X- and gamma-ray should have some essential requirements. JBCE states these as follows:*

- *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 a cooling system and the whole device size becomes too large or the device cannot be realized. It is practically very important.*

JBCE is applying for the renewal of the exemption of cadmium in detectors, because they meet *"the above four technical requirements and are 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."*

In the summary JBCE also states that "So far only a few semiconductor materials, such as silicon (Si), amorphous selenium (a-Se), germanium (Ge), CdTe and CdZnTe have been used as the direct conversion type detectors and some other semiconductors are the new candidates. However, only CdTe or CdZnTe 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.

Summary of renewal request by COCIR (2020a)

COCIR (2020a) request the exemption renewal for lead and cadmium for 7 years for cat 8 for medical devices other than in-vitro medical devices and for monitoring and control instruments other than industrial monitoring and control instruments.

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 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 γ-radiation imaging with PET (Positron Emission Tomography) and SPECT (Single Photon Emission Computed Tomography). 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 CdTe and CdZnTe 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 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.

4.2. Technical description of the requested exemption

4.2.1. Amount of cadmium and lead used under the exemption

The applicants state that a CdTe semiconductor contains 46.7 % cadmium and in a nominally Cd0.9Zn0.1Te semiconductor are 43 % cadmium.

COCIR (2020a) state further that lead metal (99.9 %) is in ionisation chamber coatings.

According to JBCE (2020a) and COCIR (2020a), quantity of cadmium is taken from a study carried out for the European Commission on the possible inclusion of categories 8 and 9 in scope of RoHS in 2006 [Goodman, Paul (2006)] and assumes that the annual amount of 300k g has doubled since 2006.

COCIR (2020a) state that 1.6 kg lead enter the market per year. The quantity calculation leading to that number by a manufacturer of ionisation chambers is confidential.

Therefore, the amount of substance that will enter the market is:

- 600 kg cadmium per year
- 1.6 kg lead per year

4.2.2. Technical description of the exemption and use of restricted substance

The restricted substances for this exemption are cadmium, mercury and lead. Mercury is no more needed for this exemption. Cadmium is used in flat panel detectors for X- and gamma rays and lead are used in ionization chambers to regulate x-ray radiation. Both substances can be used simultaneously in medical applications, but not necessarily. Therefore, in the following, the substances will be described and treated separately due to their slightly different areas of applications.

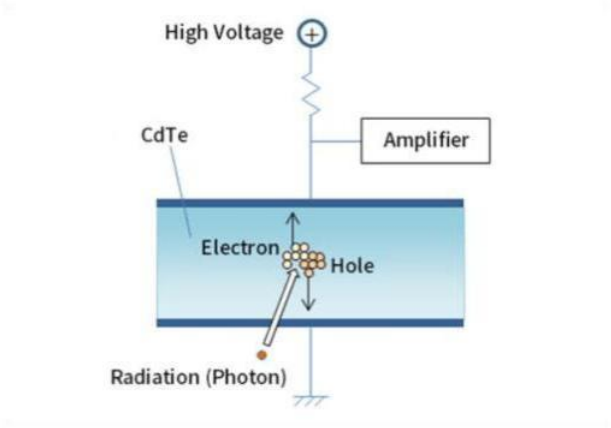
Cadmium in detectors for ionizing radiation

In order to decide which substance is the best fit for a detector of X- and gamma rays, four requirements are stated by the applicant JBCE. As mentioned above, a detector needs high sensitivity, high spatial resolution, high energy resolution and room temperature operation.

<u>High Sensitivity</u>

JBCE explains when an irradiated photon such as x- or gamma ray is absorbed in the crystal, it generates the electron-hole pairs. The electrons and the holes are driven by the internal electric field to the anode and the cathode electrode, respectively (see Figure 4-1). Through amplifying the electrical charge in the read out circuit, the photon can be detected.

Figure 4-1: Functional principle of CdTe semiconductor radiation detector



Source: (JBCE 2020a)

The semiconductors with high densities and high atomic numbers show the highest absorption efficiency as shown in Table 4-2.

Table 4-2: Physical parameters and performance of semiconductor radiation detectors

related pefromance		Si	a-Se	Ge	GaAs	CdTe	CZT	HgI_2	TlBr
Sensitivity	Density (g/cm^3)	2.33	4.39	5.32	5.32	5.85	5.8	6.36	7.56
	Atomic number	14	34	32	31, 33	48, 52	48,30,52	80, 53	81, 35
	Absorption (%) of 100keV X-ray by 1mm thick detector	4%	24%	26%	26%	62%		89%	95%
Energy Resolution	Electron mobility lifetime product (cm^2/V)	0.42 77K	$3x10^{-6}$	0.72 77K	10^{-4}	$2~3x10^{-3}$	$10^{-3}~10^{-2}$	$1x10^{-4}$	$3x10^{-3}$
	Hole mobility lifetime product (cm^2/V)	0.22 77K	$6x10^{-5}$	0.84 77K	$4x10^{-5}$	$3~5x10^{-4}$	$~10^{-5}$	$4x10^{-5}$	$~10^{-4}$
	Energy Resolution at 122keV (keV)	0.55 77K	-	0.4 77K	-	3.5	4.4	3.2	6.1
	Energy Resolution at 662keV (keV)	0.9 77K	-	0.9 77K	-	7.5	11.8	5.96	11.2
Room Temperature Operation	Band gap (eV)	1.11	2.3	0.665	1.43	1.44	1.44~1.6	2.13	2.68
	Resistivity (Ωcm) at 300K	$2.3x10^5$	$1x10^{12}$	47	$1x10^9$	$1x10^9$	$1x10^{10~11}$	$1x10^{13}$	$1.5x10^{10}$
Toxicity[55]	LD50 (mg/kg)	3,160	6,700	—	>15,000	>15,000		18	35[56] LDLo
	Toxicity(oral) GHS category	Not a dangerous sunstance	3	Not a dangerous sunstance	—	4		2	2

Source: (JBCE 2020a)

Spatial Resolution

The spatial resolution is mainly important for the imaging detector because the higher the spatial resolution is the clearer the image of the detector will be.

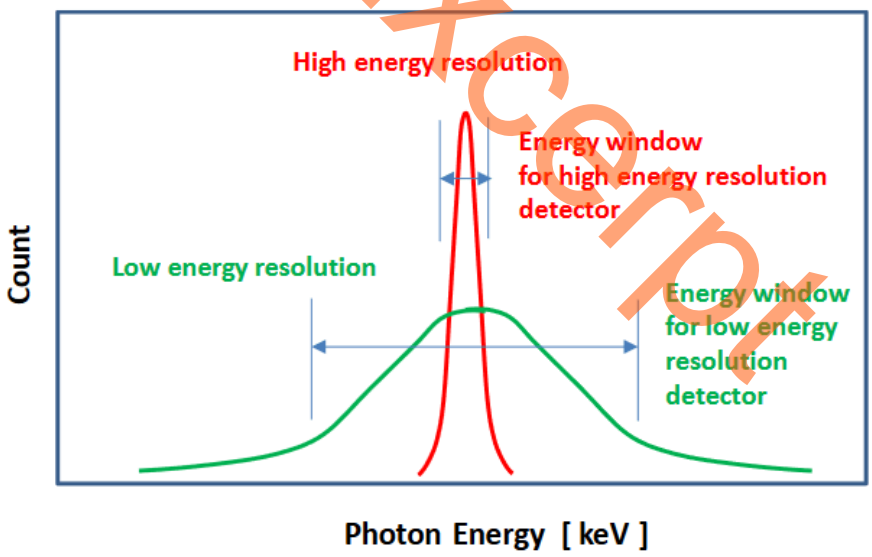
JBCE describes that *the radiation is directly converted to the electric charge, this type is called Direct Conversion type. The electric charge can reach the pixel electrode right below the absorbed position without spreading, so the sharp image can be obtained. An appropriate semiconductor thickness can be selected by the energy of photon without the risk of blurring the image. The alternative of an indirect conversion type is using a scintillator and has a lesser spatial resolution.*

Energy Resolution

JBCE explain in the application that *the energy resolution of the detector is determined by the mobility–lifetime products (μτ-products). If the Mobility Life-time Product (cm2/V) value is higher the charge collection increases, which improves sensitivity.*

If the detector has higher energy resolution, sharper image can be obtained by using the narrower energy window as in Figure 4-2.

Figure 4-2: Schematic of the relation between energy resolution and energy window



Source: (JBCE 2020a)

Room Temperature Operation

Leak current can be minimized if the detector is cooled down to liquid nitrogen temperature. Cooling down is costly and elaborate. *JBCE state this with the example of Ge in their application. But other semiconductor detectors can be used in room temperature due to the larger band gap and high resistivity. If the bandgap is not high enough, electrons in the*

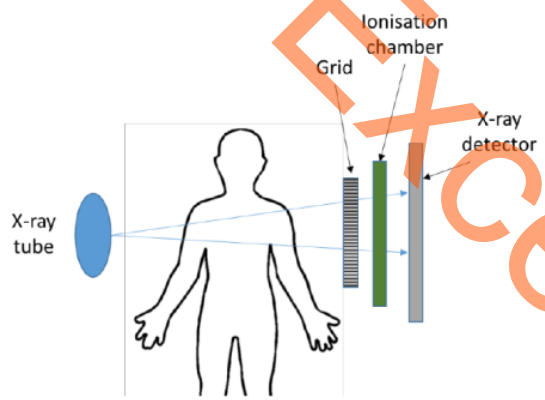
valence band are easily activated to conduction band due to the thermal energy and the leak current increases. This leak current becomes the cause of the noise.

Lead in ionisation chambers

COCIR (2020a) state that *ionisation chambers measure the quantity of X-radiation for automatic exposure control to ensure that the correct radiation dose is used to obtain a clear image. These are used in most X-ray imaging systems to compensate for the thickness and density of the parts of the patient being examined. Figure 4-3 shows the position of the ionisation chamber within the medical X-ray system schematic.*

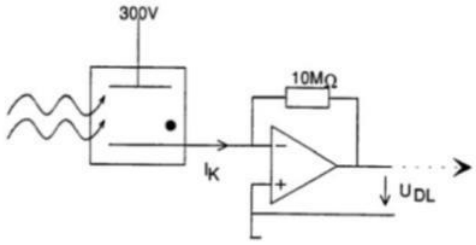
Lead is used as the negative electrode of the ionization chamber. X-rays ionise the air inside the chamber which allows secondary electrons to be emitted from the negative lead coated electrode and travel to the positive electrode. This generates a current through the chamber and the associated circuit, which determines the quantity of ionisation in the chamber from the X-radiation exposure. A typical circuit is shown in Figure 4-4.

Figure 4-3: Position of ionization chamber within the medical X-ray



Source: COCIR (2020a)

Figure 4-4: Principle of operation of an ionization chamber



Source: COCIR (2020b)

The chambers monitoring circuit include a capacitor that is charged at a rate which is determined by the quantity of ionisation in the chamber from the X-radiation. When it is charged to a certain voltage, it initiates current flow that actuates a contactor which shuts down the X-ray tube and stops X-ray exposure.

X-ray ionisation chambers are made of plastics which are transparent to X-rays and have printed graphite patterns as the positive and negative electrodes (graphite is also

transparent to X-rays). The negative electrode is then coated using physical vapour deposition (PVD) with a 3µm thick coating of lead (effectively transparent to X-rays at this thickness).

4.3. Justification for the requested exemption

4.3.1. Substitution and elimination of cadmium in detectors for ionizing radiation

Both applicants state that the substitution of cadmium leads to different semiconductor detectors. *All detectors worth considering have less energy and spatial resolution, need more radiation or need to be cooled, which means that radiation doses for patients get higher and radiation time increases.* JBCE (2020a) gave a comparison of radiation detectors used for X-ray detection (see Table 4-3).

Table 4-3: Comparison of radiation detectors

	Direct Conversion Type							Indirect Conversion Type
	Si	a-Se	Ge	GaAs	CdTe, CZT	HgI_2	TlBr	
Sensitivity	X	X	X	X	O	O	O	
Spatial Resolution	O	O		O	O			X
Energy resolution	O	×	O 77K		O	O	O	
Room temperature operation	O	O	X	O	O	O	O	
Toxicity						X	X	
Note			Cooling System required			Minamata convention	Very toxic material	

Source: (JBCE 2020a)

COCIR (2020a) write in their renewal application that *comprehensive research by a medical equipment manufacturer has evaluated semiconductors for CT (Computed Tomography) detectors. This work assessed 23 materials by assessing variables such as their absorption performance, count rate, diffusion radius (affects spatial resolution) and charge carrier loss (likelihood that an X-ray results in a charge reaching the pixelated electrode).Elements with k-edge of 80 –90 keV were reported to be less suitable for CT as this is close to the X-ray energy used for CT, which makes mercury compounds (83.1 keV) and lead compounds (88.0 keV) less suitable. This assessment resulted in three materials that are potentially suitable; CdTe, lead sulphide and germanium, however of these, lead sulphide and germanium must be cooled to low temperature which requires additional, quite bulky, cryocooling equipment or the use of liquid nitrogen. Liquid nitrogen cooling is not technically practical for a CT detector as the detector rotates around the patient. Also, of the 23 semiconductors assessed, only a few materials, including CdTe are commercially available of suitable thickness and size.*

4.3.2. Substitution and elimination of lead in ionization chambers

COCIR (2020a) state that *the substitution of lead in ionisation chambers is only possible with tin. But substituting the lead by tin means a redesign of the imaging systems, which only can be done by new designs and not on existing systems. This can take up to 10 years.*

COCIR (2020a) explain in the application that *light elements (such as graphite) generate very weak signals (graphite emits only 2 % of the emission from lead of similar thickness) and the signal is too small to give accurate control. As each element emits secondary electrons with different energies, there is no possible drop-in replacement for lead as every alternative element will generate a different signal. As the ionisation chamber design, control circuits and especially the calibration curves were developed with lead, it is not possible to use a different metal coating and achieve the same automatic exposure control; patients' images will be over or under-exposed if a different metal were used.*

COCIR also gives a comparison of ionisation chambers to phototimers. Ionisation chambers have mostly replaced the previously used method of automatic exposure control using phototimers. Phototimers use scintillator panels that convert X-rays into light and then the light output is measured with photomultipliers or photodiodes. As most X-rays should be absorbed to be measured, these are positioned after the X-radiation has passed through the patient. This has disadvantages that have resulted in the change to ionisation chambers, as summarised in Table 4-4.

Table 4-4 Comparison of ionisation chambers with phototimers

Characteristic	Ionisation chamber	Phototimer
Position	After X-rays emerge from patient.	After X-rays emerge from patient.
Effect on X-ray beam	Does not block X-rays so no scattering or image generated	Must absorb radiation to measure dose. Scattering does occur which requires lead shielding and can affect image quality
Behaviour with implants	No effect as energy from X-ray tube is measured before reaching patient	Can block X-radiation so that patient receives a dangerously high dose and image is over-exposed
Shielding	Not needed	Lead shielding required

Source: (JBCE 2020a)

If implants block X-radiation, the phototimer registers a too low intensity of the X-ray which as a result increases the intensity so that the patient may be exposed to a dangerously high dose.

COCIR (2020a) compare the detection efficiencies and detection limits of commonly used types of detectors. COCIR (2020b) give a few examples concerning the comparison of different detectors. The data in Table 4-5 of COCIR's exemption renewal request shows that the efficiency of CdTe and CdZnTe detectors is 60 % whereas flat panel detectors with scintillators are only 40 %. This allows the radiation dose to be reduced by about 30 %. In fact, the difference is even larger because, as shown in

Table 4-6, CdTe and CdZnTe semiconductor detectors can detect single photons, so are able to count number of photons per pixel, in comparison a flat panel with scintillator has a detection limit of 104 photons/mm. Therefor it is much less sensitive at low levels of X-ray energy. To be able to achieve a reading with a flat panel with scintillator patients would have to be exposed for longer due to the lower sensitivity.

Table 4-5: Detection efficiency of commonly used types of detectors

Material	Detection Efficiency %
Silicon	~5%
Sodium iodide scintillator	~40%
Cadmium telluride and cadmium zinc telluride	~60%

Source: COCIR (2020a)

Table 4-6: Detection limits of common types of X-ray detection media

Detector	Detection limit, photons / mm^2.
Photographic film	10^6
Flat panel detector with scintillator	10^4
CMOS CdTe semiconductor detector	1

Source: COCIR (2020a)

COCIR (2020b) further state that a recent verification test during clinical lung imaging using CdZnTe confirmed that exposure can be reduced to 1/5 (20 %) of the radiation dose, compared to state-of-the-art non-CdZnTe technology. Other sources from a preclinical prototype CT based on CdTe sensors show for certain applications a reduction in dose of about up to 30 % at the same image quality.

4.3.3. Roadmap towards substitution or elimination of cadmium in detectors for ionizing radiation

Both applicants state that they believe that *there will be no substitute available within the next 7 years and even after that the development of a new detector will last more than 20 years.*

COCIR (2020a) further state that *the current development of GaAs can be compared to the stage of development of CdZnTe in the 1990's due to its performance and yield. Development of CdZnTe required since the 1990s an additional 10 years of development for niche applications and 25 years for mainstream medical applications such as CT.*

COCIR further describe that *for CT detector application (energy range 20 keV to 140 keV) one would need a sensor of 5 mm in thickness (for comparable absorption to 1.6 mm CdTe). Such a thickness in a quality being sufficient for CT X-ray detectors is not yet available – even at research level. For manufacturing GaAs in X-ray detector grade quality, one has in principle two possibilities, either slicing a big ingot in wafers and performing post-growth doping with chromium or by using epitaxial growth techniques. Both, the Post-growth doping and the epitaxial growth are limited to low thickness as of about 500 µm^2. This is still less than the required 5 mm. All other disadvantages of GaAs demonstrating that GaAs is inferior to CdTe and CdZnTe. The other materials stated are even further away from being commercially available, in addition to the fact that HgI2 or PbI could not be used without an exemption.*

4.3.4. Roadmap towards substitution or elimination of lead in ionization chambers

The substitution of lead in ionization chambers is only possible with tin and needs a redesign of the system. Therefore COCIR (2020a) state that designing a new X-ray system is extremely complex and typically takes over 10 years from design to construction of prototypes, testing, clinical trials and gaining Medical Device Regulation approval by a Notified body. Each manufacturer is able to develop one new system at a time (due to limitations on the availability of trained engineers) and each manufacturer will have many systems designed for different purposes.

4.3.5. Environmental arguments and socioeconomic impacts

The applicants state that according to WEEE directive requirement, the equipment shall be collected by the responsible company which is in the WEEE registration list and passed to the recycler who shall treat them adequately under the WEEE requirement.

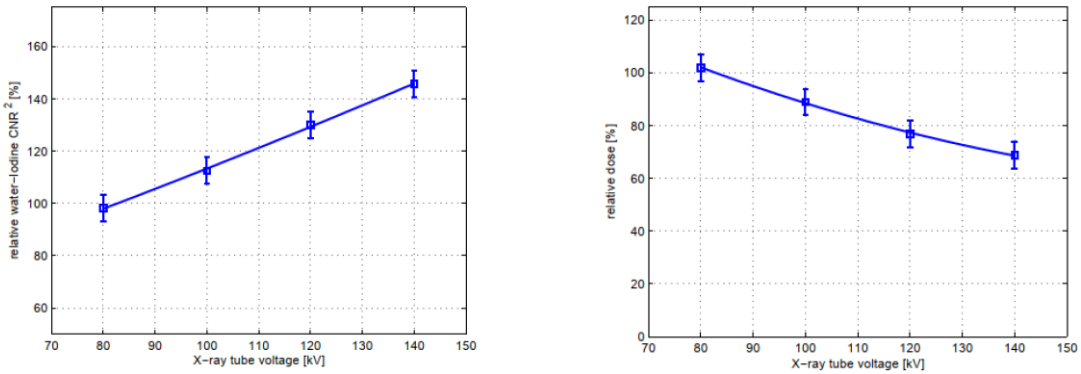
In case of expensive medical devices such as CT, SPECT and PET, they can be refurbished or reused. Even more the materials of old detectors can be recycled in order to produce new detectors.

(JBCE 2020a) state that 480 kg of cadmium can be reused and 120 kg of cadmium can be recycled from the devices which are currently on the market when they are treated once they come back from the market in the coming years.

Additionally, COCIR (2020a) confirms that 480 kg cadmium and 1.3 kg lead can be reused and 120 kg cadmium and 0.3 kg lead can be recycled. JBCE (2021) also gives a calculation

on how the radiation dose of a CdTe based detector can be reduced by optimizing the contrast to noise ratio (CNR2) to the tube voltage. The dose with CdTe photon counting detector can be reduced by 32 % for the same image quality that is obtained by a conventional detector at 140 V, see Figure 4-5.

Figure 4-5: Optimized radiation dose of CdTe detectors – an example



Source: JBCE (2020b)

JBCE (2020a) further state that *without the possibility of using a Cd-based detector, the diagnosis in medical field becomes poor and the radiation exposure risk to the patient and the medical staff increase. This applies not only to the medical field, but in other applications, such as non-destructive testing, food inspection, baggage inspection, etc. For the society, the accuracy of the inspection is absolutely necessary, and the risk of the radiation exposure should be decreased at the same time.*

COCIR (2020a) adds that *possible substitutes of a detector for ionised radiation require higher radiation doses, which can be harmful to patients, and inferior image quality which may prevent early or accurate diagnosis.*

COCIR (2020a) further states that the use of a ionisation chamber is not a reliability issue. But the chamber is used to control the X-ray imaging properly and to receive a well exposed image immediately. Otherwise repeated imaging exposes the patient unnecessarily with radiation.

4.4. Critical review

4.4.1. REACH compliance – Relation to the REACH Regulation

Art. 5(1)(a) of the RoHS Directive specifies that exemptions from the substance restrictions, for specific materials and components in specific applications, may only be included in Annex III or Annex IV "*provided that such inclusion does not weaken the environmental and health protection afforded by*" the REACH Regulation. The article details further criteria which need to be fulfilled to justify an exemption, however the reference to the REACH Regulation is interpreted by the consultants as a threshold criterion: an exemption could not be granted should it weaken the protection afforded by REACH. The first stage of the evaluation thus includes a review of possible incoherence of the requested exemption with the REACH Regulation.

Lead

Lead is a substance of very high concern but so far, aside from a few specific compounds, has not been adopted to REACH Annex XIV. The fact that lead is a candidate substance therefore at the time being does not weaken the *environmental and health protection afforded by"* the REACH Regulation if the requested exemption would be granted/renewed.

REACH Annex XIV (2021)[5] lists a few substances which include lead compounds, the placing on the market and use of which would require an authorisation in the European Economic Area:

- *Lead chromate (entry 10);*
- *Lead sulfochromate yellow (entry 11);*
- *Lead chromate molybdate sulphate red (entry 12);*

The application in the scope of the exemption at hand use lead only and not any of the above lead compounds.

REACH Annex XVII (2021) also contains entries restricting the use of lead compounds:

- *Entry 16[6] and entry 17[7] restrict the use of lead carbonates and lead sulphates in paints;*
- *Entry 19 refers to arsenic compounds but includes a few lead compounds[8] such as lead arsenide and restricts their use as anti-fouling agent, for treatment of industrial water or for the preservation of wood;*

The above applications are not applicable to the use of lead in the applications in the scope of the exemption at hand.

- *Entry 28[9] addresses substances which are classified as carcinogenic. In this context, it stipulates that various lead compounds, e.g. lead chromate, shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*

[5] ECHA, https://echa.europa.eu/authorisation-list?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[6] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[7] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[8] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[9] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

- *Entry 30[10] addresses substances which are classified as reproductive toxicants. Like for entry 28, entry 30 stipulates for some lead compounds that they shall not be placed on the market, or used, as substances, constituents of other substances, or in mixtures for supply to the general public;*
- *The above restrictions are not applicable to the use of lead in the exemption at hand. The substances are part of an article (professional use medical devices) and thus are not placed on the market or used as substances, constituents of other substances or mixtures supplied to the general public.*
- *Entry 63[11] restricts the use of lead and its compounds in jewellery, e.g. wristwatches, and in articles or accessible parts thereof that may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children. This entry lists many lead compounds, including lead sulphide (PbS) and lead selenide (PbSe).*
- *Entry 72[12] stipulates that lead and various lead compounds listed in entries 28, 29 and 30 shall not be used in textiles, clothing and foot wear.*

Lead in the scope of the exemption at hand is thus not used in wristwatches or any other jewellery in the scope of entry 63, nor are conditions foreseeable where lead components or the related equipment may be placed in the mouth by children. Further on, EEE in the scope of the RoHS Directive 2011/65/EU is excluded from the scope of entry 72.

No other entries, relevant for the use of lead in the requested exemption could be identified in Annexes XIV and Annex XVII. Based on the current status (October 2021) of these Annexes, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if the respective criteria of Art. 5(1)(a) apply.

Cadmium

With regards to **Annex XIV of the REACH Regulation**, cadmium in general or in compounds is not mentioned in the list of substances that require an **authorisation** for use.

With regards to **Annex XVII of the REACH Regulation**, cadmium is mentioned in a few of the listed restrictions.

Paragraph 1 of entry 23[13] of Annex XVII refers to cadmium and several of its compounds including cadmium telluride. Under this entry, several restrictions are mentioned for cadmium and the compounds, among others:

1. *A list of various polymers in which Cd may not be used unless required in colour for safety reasons.*

[10] ECHA, https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[11] ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6

[12] ECHA, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20210825&from=EN:#page=546

[13] C.f. ECHA, https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518

2. *Shall not be used for cadmium plating[14] metallic articles or components of articles used in equipment and machinery in certain branches and applications, e.g. cooling and freezing, food production, etc.*
3. *Shall not be used in brazing fillers unless used for safety reasons*
4. *Shall not be used or placed on the market if the concentration is equal to or greater than 0.01 % by weight of the metal in metal beads and other metal components for jewellery making, or metal parts of jewellery and imitation jewellery articles and hair accessories, e.g. in wristwatches.*

In the scope of the exemption at hand, Cd(Zn)Te is neither used in polymers nor in platings or as brazing filler, and its use under the exemption is not related to jewellery. The above stipulations are therefore not applicable.

Due to their carcinogenicity, *entry 28[15] of Annex XVII does not allow the placing on the market, or use of various substances as such, as constituents of other substances, or in mixtures. Various compounds are mentioned in this respect, including among others cadmium sulphide and cadmium nitrate.*

Neither CdTe nor CdZnTe are mentioned so that the restrictions related to entry 28 do not apply.

Entry 72[16] lists substances which are classified as carcinogenic, mutagenic or toxic for reproduction. It refers among others to cadmium and its compounds as listed under entries 28, 29 and 30 (germ cell mutagenic substances) and restricts their use in clothing and textiles. The entries list several cadmium compounds, among others cadmium sulphide and cadmium nitrate.

Like entry 28, this entry does not address Cd(Zn)Te as it is applied in exemption 1.

To conclude, none of the entries currently listed under REACH would apply to the case at hand. The Use of Cd in Cd(Zn)Te detectors cannot be considered to weaken the protection afforded by REACH. The exemption can therefore be renewed if the relevant stipulations of Art. 5(1)(a) apply.

4.4.2. Substitution or elimination of cadmium in X-ray detectors

According to the applicants, the elimination or substitution of cadmium in the radiation detectors would result in the use of different semiconductor detectors or even use a scintillation detector. The applicants discuss that both alternatives would be followed by complete redesign of the system and a lower resolution, which would mean longer

[14] 'Cadmium plating' means any deposit or coating of metallic cadmium on a metallic surface

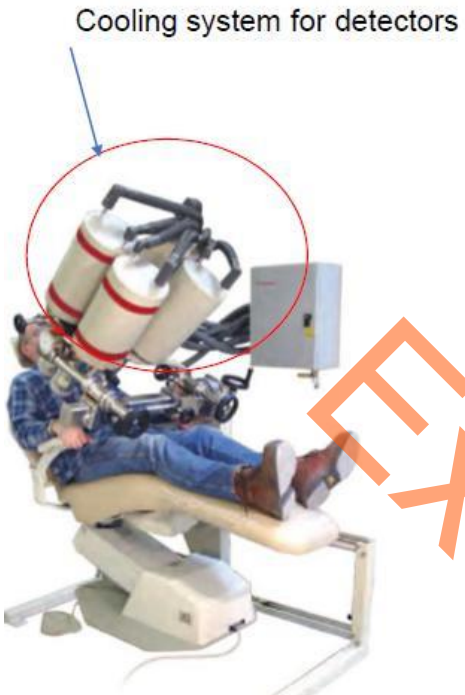
[15] ECHA, https://echa.europa.eu/de/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

[16] ECHA, https://www.echa.europa.eu/web/guest/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_javax.portlet.action=searchDissLists

exposition times and thus higher exposure to X-rays and lower quality of X-ray photographs, c.f. section 4.3.1 This is highly impractical for medical und security purposes.

The applicant was requested to give an example for an alternative detector that needs cooling. JBCE (2021) show how a cooling system of a lung counter. In this case, the measurements are made with a static detector, but are much more difficult to use with rotating detectors like used in CTs.

Figure 4-6: Lung counter with a cooling system



Source: Canberra[17] in JBCE (2020b)

The applicant described the advantages of CdTe detectors and was asked to provide more details substantiating these statements.

COCIR (2020b) add on request that for the applications described in the exemption request the use of a cooling system is not technically practical. *Additionally, those materials which use Germanium and which require cooling, have a higher diffusion radius which leads to a reduced spatial resolution (pixel size) compared to Cd-based materials, so could not be described as achieving the same performance. CdTe and CZT are wide band gap room temperature semiconductor radiation detectors that do not need cooling.*

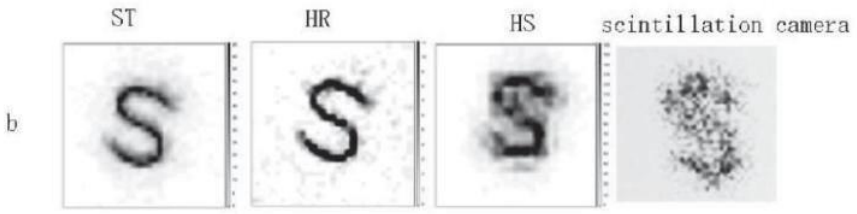
JBCE (2020b) also give an example of the comparison of a CdTe based detector with a conventional NaI (sodium ionide) scintillation camera[18].

In Figure 4-7 it is described that the three on the left were taken with the CdTe gamma camera and the one on the right was taken with conventional NaI scintillation camera.

[17] C.f. Canberra in JBCE 2020

[18] JBCE 2020b cites the following article: T Oda, et all. “Evaluation of Small Semiconductor Gamma Camera” Kakuigaku (NuclearMedicine) 6:pp 1-12, 2009

Figure 4-7 Comparison CdTe based detector with NaI scintillator camera



Source: JBCE (2020b)

This example shows that the resolution of the CdTe detector is much better than the one from the NaI scintillator and JBCE state that the radiation dose is halved.

Both applicants refer to a new detector that is still in development. It is a detector based on a Perovskite hybrid, which is a lead based crystal. This substance is already used in solar cells, which are not included in the scope of RoHS. There is a project called PEROXIS[2] that works on the development for this detector with the aim to develop the next generation of highly sensitive X-ray detectors that will enable better diagnostics and treatment for better patient outcomes. The project is due to finish by the end of 2022. JBCE (2021) and COCIR (2021a) request to take into account this development and include lead into the scope of the future exemption IV-1.

COCIR (2021a) say that such detectors might already be placed on the market in 2026. They claim that lead should therefore remain in the exemption wording so that no new exemption would have to be requested for these detectors prior to 2026. They also state in the context of these new detectors that there may be other applications of lead in detectors out there and that probably the manufacturers do not even know that the wording is going to be changed so they ignore they should come out.

The applicants upon request could not give details as to the performance of the lead containing Perovskite detectors compared to CdTe or CdZnTe detectors. In the consultants' point of view, new developments can be taken into account in principle. In the case at hand, however, the applicants could not provide properties showing that these detectors have superior performance or other advantages compared to the cadmium detectors for which the exemption renewal was requested. In the absence of such evidence, the consultants cannot recommend the exemption to be renewed for lead in line with Art. 5(1)(a). COCIRs' request in this context cannot be followed to further on including the use of lead in detectors in the exemption scope because manufacturers or users of such detectors did not know of the exemption review. Following this proposition would in consequence block revocations or changes of exemptions and shift the responsibility of producers and users to follow up on the legislation of relevance for their activities to the consultants and the COM.

The consultants therefore recommend that COCIR, JBCE or other applicants request a new exemption or the amendment of exemption 1 when they can substantiate their application with sufficient evidence and in time to enable them to be placed on the market latest after the two year approval phase. The actual performance and properties of lead-containing Perovskite detectors should be clear latest, probably even before, the beginning of this approval phase.

4.4.3. Substitution or elimination of lead in ionization chambers

According to COCIR (2020a), elimination or substitution of lead in ionisation chambers is possible by tin. COCIR state that "tin is the only alternative to lead which one manufacturer has been able to develop for use in newly designed and calibrated imaging systems. Secondary electron generation differs significantly between lead and tin. As a result, tin-based chambers can be installed only in new designs of x-ray systems whereas lead-based chambers must be used in all other existing X-ray systems on the market, which are most existing systems."

COCIR was asked since when these lead-free chambers are available, which manufacturer developed this system and in which X-ray devices it was used. *COCIR (2021b) said that this new technology has been developed by Siemens Healthcare GmbH for a few new radiology systems by use of a lead-free chamber. The first x-ray model using this new technology was placed on the market in 2013 by Siemens. To date there are no technical parameters which preclude the use of lead-free ionization chambers beyond the requirement that the system is specifically designed for being used with these lead-free chambers (to allow for different calibration algorithms etc.). After such a redesign taking into account the specific properties of the ionization chamber, each X-ray can be operated with this lead-free ionization chamber.*

COCIR (2021b) highlight that lead-free chambers are not available on the market to be purchased. It is a new technology that has been developed by one single manufacturer. Most manufacturers of x-ray devices simply purchase lead-based ionization chambers. The time to develop a similar technology and to ensure it is reliable, should also be taken into account.

Development of the chamber itself, the generator and the radiology systems, would need to be undertaken. The resulting changes in the image chain (X-Ray-Tube, Generator, Ionizing Chamber, Software and Calibration) effectively results in a new device as changing in one part affects the others. Every combination of the available flat panel detector energy dependent behaviour of the chain radiation-ionization chamber-generator-detector would have to be measured/found. After having found the right combination values the calibration algorithm has to be developed in the generator/system-software.

The development on system level firstly requires adaptation of the adjustment, calibration procedures and eventually reflecting those in the system software (system service software). The entire component chain (chamber, generator and system service software) then would need to be integrated, tested and undergo regulatory approval tests such as EMC, electrical safety typically by authorized test houses.

For Siemens Healthcare GmbH which has models utilising lead-free chambers the following timeframes could be expected for the redesign of a device:

- *Development: Integration of chamber and definition of interface electronic (value): 3-4 years*
- *Development of the generator respectively modification of the generator electronics: 2-3 years*

However, manufacturers which do not have this experience or an already working lead-free chamber , could take significantly longer as the function lead provides to such devices is so integral to the function of the device.

For global approvals, after successful testing of the component changes, results need to be shared with specific authorities for renewal of the respective country licenses, which can require confirmation test by local authorities e.g. China.

COCIR (2021b) state that the innovative part is always a small one. The ionization chamber is part of the image chain (tube, generator, chamber, collimator, detector). This technology has a design cycle that is far longer than the device itself and is used unchanged in successive generations. The chamber in particular plays a critical safety role and, for instance, unlike tubes and detectors, cannot be changed without redesigning the whole image chain. To use lead-free ionization chambers the whole calibration process of the image chain for every system variation would have to be to be significantly changed. It is a huge development effort. First have to find out a way to design and manufacture such chambers, or work with manufacturers of lead-free chambers, in a way to ensure absolute reliability.

Secondly, the redesign of the image chain is not even possible at the level of single product redesign as it would require more time than what is required to redesign the product (it can be assimilated to design a new car engine, versus redesigning a car model. Cars are designed to adapt to the new engine, it is not the engine that is redesign to adapt to cars).

Therefore, the introduction of such lead-free technology could only happen at a very slow pace, at the moment when companies launch a redesign of the image chain. It can be additionally considered that the lead-free technology does not offer any clinical advantage compared to the lead based one.

The consultants understand the above efforts are needed, but at the same time the legal obligation to substitute or eliminate the use of lead has been established via the RoHS Directive including cat. 8 medical devices. It seems that one manufacturer has undertaken successful efforts to develop lead-free ionization chambers and operate them in newly designed X-rays devices. Since 2013, no other manufacturer seems to have followed this example.

In the light of the above, the consultants recommend renewing the exemption to leave time to ensure the reliability of lead-free substitutes by redesign of X-ray devices and develop lead-free ionization chambers if not available on the market. Given the fact that one manufacturer has lead-free ionisation chambers in use, even though not yet in all X-ray models, the exemption should be renewed for three years only. The manufacturers can by then prove compliance efforts or explain plausibly why such efforts still were not possible taking into account that one manufacturer has undertaken such compliance efforts.

4.4.4. Inclusion of ionization chambers into the scope of exemption 1

According to COCIR (2020a), *ionisation chambers measure the quantity of X-radiation for automatic exposure control to ensure that the correct radiation dose is used to obtain a clear image.* They can thus be understood as detectors and thus EEE. In this function, they might be interpreted as lead shielding. But the chambers are exposed to the radiation that passes through the patient instead of shielding the patient from X-rays, and their function prevents the generation of too much X-ray rather than shielding the patient from generated X-ray. Additionally, the lead shieldings addressed in exemption IV-5 are layers/pieces of lead metal and not EEE like the ionization chambers.

Since their function can be understood as detectors for ionization radiation, ionization chambers are covered by the current exemption 1. COCIR proposed specifying the exemption for cadmium-containing detectors and the ionization chambers, and the consultants welcome this proposal because it specifies and defines clearer the exemption scope.

Even though the ionization chambers can be interpreted as a detector for X-rays, their function is different from the cadmium-containing detectors which generate the image, while the ionization chambers control the intensity of generated X-rays. The proposed wording for the renewed exemption addressing the chambers - *Lead in coatings of ionisation chambers of X-ray detectors* – reflects the situation that the monitoring chambers are operated in conjunction with the detectors creating the image. Additionally, since the chambers were understood to be covered by exemption 1 so far, it might create confusion if they are now listed in a separate exemption. As the consultants do not see an urgent need to separate the ionization chambers, it will be kept in the scope of exemption 1.

4.4.5. Environmental arguments and socioeconomic impacts

Having a low radiation dose is a key point in protecting the patients and users of ionized radiation. The Cd-containing detectors contribute to reducing the dose and thus reduce the risk of cancer. Likewise, the usage of an ionisation chamber contributes to better control the intensity and thus the exposition to X-ray radiation.

In the consultants' view these arguments are plausible. Not renewing exemption 1 would thus have adverse impacts on health care in the EU/EEA.

4.4.6. Conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- *their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II* ***is scientifically or technically impracticable****;*
- *the* ***reliability*** *of substitutes is not ensured;*
- *The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.*

JBCE and COCIR request the renewal of exemption 1 for the maximum seven years validity period. They plausibly explain that the use of cadmium in X-ray detectors results in higher image qualities and allows reducing the X-ray dose to which patients are exposed during X-ray examinations. Compared to other detectors which do not use RoHS-restricted substances, the Cd-containing detectors are superior. The substitution of elimination of cadmium is scientifically and technically not practicable.

COCIR requests to include lead in ionization chambers into the scope of the exemption. The substitution of lead by tin in these chambers is, however, scientifically and technically practicable, even though with considerable effort since a comprehensive redesign of the entire X-ray would be required, and possibly the development of an own lead-free ionization chamber. One manufacturer has, however, already started lead substitution with first

models of X-rays placed on the market in 2013, even though not all X-ray models yet seem to have been redesigned accordingly. So far, no other manufacturers have substituted lead in ionization chambers.

In synopsis of the situation, the consultants recommend renewing the exemption since the full conversion of X-rays to operate with lead-free ionization chambers takes time to ensure the reliability of the substitutes so that the renewal should be justifiable by Art. 5(1)(a). The exemption should, however, only be renewed for three years accommodating the fact that one manufacturer has lead-free solutions available already since 2013.

4.5. Recommendation

Based on the information submitted by the applicants, the consultants recommend renewing the exemption. Substitution or elimination of cadmium in CdTe and CdZnTe detectors are scientifically and technically not yet practicable and is not foreseeable for the coming seven years.

The substitution or elimination of lead in ionization chambers is scientifically and technically practicable, but the X-ray devices need a far-reaching redesign to ensure the reliability of the substitutes. Renewing the exemption would therefore be justified by the second criterion of Art. 5(1)(a) for the Cd-containing detectors and for the ionization chambers.

Substitution or elimination of cadmium in the detectors are not foreseeable in the next seven years. One manufacturer has already started the substitution of lead in ionization chambers and has been placing first models of X-rays with lead-free chambers on the market since 2013. It is therefore recommended to grant the exemption for three years only. The consultants recommend the following wording for the exemption in agreement with the applicants.

Exemption		Scope and dates of applicability
1(I)	*Cadmium in cadmium telluride and cadmium zinc telluride detectors for ionising radiation*	Expiry on - 21 July 2028 for cat 8 medical devices others than in-vitro diagnostic medical devices, and for cat. 9 monitoring and control instruments including industrial monitoring and control instruments
1(II)	*Lead in coatings of ionisation chambers of X-ray detectors*	Expiry on 21 July 2024 for cat 8 medical devices other than in-vitro diagnostic medical devices

4.6. References

COCIR (2020a): Exemption Renewal Form - Exemption 1 Annex IV.

COCIR (2020b): Answer to Questionnaire 1 (Clarification) received at 08.09.2020.

COCIR (2021a): Answers to Questionnaire 2 from Riccardo Corridori (COCIR) to Saskia Huber (Fraunhofer IZM) received at 10.08.2021.

COCIR (2021b): Answers to Questionnaire 3 (Clarification) received at 05.10.2021.

Goodman, Paul (2006): Review of Directive 2002/95/EC (RoHS) Categories 8 and 9. Final Report July 2006, amended 19 Sep 2006. ERA Report 2006-0383. ERA Technology Ltd. Online verfügbar unter https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf.

JBCE (2020a): Exemption Request Form.

JBCE (2020b): Answer to Questionnaire 1 (Clarification) received at 01.09.2020 by e-mail.

JBCE (2021): Answer to Questionnaire 2 (Clarification) received at 25.08.2021 by e-mail.

REACH Annex XIV (2021): Authorization list, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/authorisation-list.

REACH Annex XVII (2021): List of restricted substances, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Online verfügbar unter https://echa.europa.eu/substances-restricted-under-reach.

RoHS Directive 2011/65/EU: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast). RoHS 2. European Union. Online verfügbar unter http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065.