Clarification Questionnaire for Exemption No. 27, Annex IV (renewal request)

"Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in

(a) magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or

(b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy."

Abbreviations and Definitions

MRI	Magnet Resonance Imaging
Pb	Lead

Background

The Oeko-Institut and Fraunhofer IZM have been appointed within a framework contract[1] for the evaluation of applications for the renewal of exemptions currently listed in Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

COCIR has submitted a request for the renewal of the above mentioned exemption, which has been subject to a first evaluation. As a result we have identified that there is some information missing. The questions below are intended to clarify some aspects concerning the renewal request.

Questions

1. You state that there is "*A large variety of RF send and receive coil designs are used with MRI which are designed for imaging a wide variety of body parts […].*"

   Can one MRI use all coils specific for all body parts, or is an MRI itself tailor-made for the use of one coil for a specific body part, or a limited range of coils for different body parts?

[1] The contract is implemented through Framework Contract No. FWC ENV.A.2/FRA/2015/0008 of 27/03/2015, led by Oeko-Institut e.V.

One model of MRI can be used to examine all parts of the body using many different MRI coils, each MRI coil is used to examine a unique body part or a subset of body parts in related regions of the body. To image the entire body, multiple MRI coils are needed. MRI coils are designed to be used with specific types of MRI so MRI coils from one manufacturer cannot be used in MRI of different manufacturers.

2. You explain in your exemption request that "*The current range of coils will also be needed as replacement spare parts for MRI that are placed on the market while exemption 27 is in effect. These replacement spare parts would, however, be excluded from RoHS by Article 4.4(f). Nevertheless hospitals will also want to buy additional new coils to use with their MRI, which are not replacements, and so these coils would need this exemption.*"
   The RoHS Directive defines 'spare part' as *"[…] a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored* ***or is upgraded*** *when the part is replaced by a spare part"*.

   Can the replacement of coils with new coils in MRIs put on the market before 21 July 2021 be understood as using spare parts to achieve an upgraded functionality which would then be covered by Art. 4(4)(f) as well?

The question highlights a classic problem medical imaging devices are facing when dealing with RoHS. The Directive was designed to work for domestic appliances or IT equipment where the concept of "accessory" or "spare part" is quite evident. Unfortunately, RoHS does not really work for complex devices where the same device can be considered internally by the manufacturer as a spare part or as an accessory depending on its destination. In particular, the relationship between the RoHS and MDD CE marking obligations may cause some confusion, that's why COCIR developed a guidance for manufacturers on this specific aspect[2].. The MDD considers "finished product", to be CE marked, equipment that may be considered component by RoHS 2 (and therefore no marking is needed).

The Medical Devices directive defines "Accessory" as:

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

It is very difficult to understand if the RoHS concept of „spare part" is equivalent to the MDD concept of „Accessory" but on the other end, for the specific case of coils, the suggestion to consider the use of different coils as an expansion of capacity of an existing device, does not really seem to fit the definition of "spare part" that includes the concept of "replacing".

Anyway, even if it was accepted that coils can be considered "spare parts", such a solution would not solve the need for this exemption. As stated in the dossier, it would take significant time before all coils model can be redesigned so to provide hospital with all the equipment they need for proper diagnosis. After June 2020, date of expiration of exemption 27, not all coils that are needed by hospitals would be available in the new lead-free design. It is even possible that certain coils cannot be redesigned with lead-free printed dielectric materials.

[2] *COCIR Guidance "RoHS 2 Obligations for components and accessories, July 2014"*

3. You state "[…] *that magnetic metals such as nickel, even in very small electronic components, can have a magnetic susceptibility that is sufficient to degrade the image quality reducing the ability to detect small features such as tumours or blood clots.*"
   You say that "*Some MRI components are fairly large […] and so the magnetic versions would contain large amounts of nickel, which would […] distort images. Versions of these components containing very small amounts of magnetic metals such as nickel may be acceptable if they do not cause image distortion.*" It seems that even small amounts of Nickel can have detrimental effects, but possibly not in all circumstances.

   a. Under which conditions would such components with small amounts of nickel not cause image distortions?

The only circumstance is where there are identical components arranged uniformly around the patient so that their effect on the image is cancelled out. This is not usually possible.

   b. Would the small amounts of nickel improve the solderability and reliability sufficiently to allow the use of lead-free solders?

Possibly. Exemption 32 of Annex IV is for a specific type of MRI application in which many identical components are arranged uniformly around the patient. This exemption is no longer required because these nickel plated components can be used with lead-free solders.

4. Can effects of distortions in the magnetic field be compensated by the signal evaluation software if the distortions are "constant", i.e. occurring systematically e.g. caused by the use of components with nickel?

This is not possible

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out as 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.