Questionnaire for Further Clarification

Exemption Request "Lead in solders used in mobile medical equipment"

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2)by the European Commission.

You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check. As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online stakeholder consultation on your request. Therefore we kindly ask you to provide answers for the following questions and to reformulate your request if necessary.

Questions

1. The long life time of medical equipment of 20 years and more is a pillar in the justification of the COCIR exemption request. Is this actually true for mobile medical equipment? Does such equipment actually have such long life times? To what extent the (physical) life time differs from the expected useful life time? Please provide evidence.

"Physical life" – This varies depending on the type of equipment. Any that are transported in ambulances will be mobile and so suffer from vibration about 30% of their lifetimes. This will include CPR, CO2 monitors and portable ventilators. Equipment transported around hospitals will be mobile for less time, we estimate about 5% of the time and this includes some ventilators and most mobile ultrasound (~5% are transported in vehicles). Patient worn devices may be carried by patients for up to 50% of the time but for these devices, being dropped is a more likely cause of failure when being dropped 5 or more times could be sufficient to cause failure of a lead-free soldered version. All ambulance carried equipment can be dropped by paramedics when they reach a patient and this can occur many times in the life of these products. All mobile hand carried equipment including devices carried in vehicles is frequently knocked when removed and replaced into vehicles, especially in emergency situations This can occur several times every day and tests has shown that this imposes very high g-forces that is a major cause of solder bond failure. Vehicle transported devices will also suffer from severe thermal cycles during their lifetimes than those used in buildings. It is also fairly common for manufacturers to

upgrade mobile medical devices to add functionality. Manufacturers can do this every 7 or 8 years up to three times with a product giving a lifetime of ~20 years.

"Lifetimes" – COCIR has indirect evidence that mobile medical devices are used for 20 years. It is common for manufacturers to provide warranties and have service contracts. It is common for these contracts to last over 18 years.

2. Exposition to vibrations and shocks from dropping the equipment is another pillar of COCIR's justification. Why can't the electronics be better protected to mitigate this problem and thus enable the reliable use of lead-free solders?

Manufacturers already do everything that is possible and are carrying out research into new designs that will be more resilient. This research is expected to take many years but it is hoped that eventually, this exemption will no longer be needed. There are however several limitation that prevent better protection being added to mobile devices. With some devices such as CO2 monitors and some types of ultrasound transducers, the size of these is severely limited by the positions in which they are used. The ultrasound transducers' aperture must fit between patient's ribs so extra protection cannot be added and CO2 monitors must fit onto the patient's neck and face. Several other types such as mobile ultrasound, potable monitors, automated CPR and mobile ventilators are already fairly heavy and adding any additional weight would be unacceptable as they need to be carried by hospital staff and paramedics, often with other equipment. Maximum weight is a severe limitation on adding additional features to give protection to delicate circuits. Devices worn by patients who are elderly or unwell must be as light as possible and so addition of substantial protection against shock from being knocked or dropped is not feasible.

3. Please provide a substantiated calculation of the amounts of lead (worldwide and in the EU) that would be used in case of granting this exemption.

The quantity of lead used in MMDs is calculated from the estimated quantity of solder used on printed circuit boards of MMDs, the number of these PCBs used in each device and annual EU sales of each device. The quantity of solder used on each PCB is not normally measured and so a contract manufacturer has estimated that each mobile medical device PCB will on average will consume about 11 grams of SnPb during processing and this also includes the amount of SnPb plating for the components on the PCB. There is of course considerable variation with some very small PCBs having much less and some very large high density boards containing substantially more solder.

The number of assemblies is multiplied by 11 grams of SnPb and by the EU sales volume, then divided by 1000 to obtain kilograms of lead solder used in MMD placed on the EU market annually. The mass of solder is multiplied by 37% (SnPb 63/37) to obtain the amount of lead which will give us the total consumption of Pb in EU.

The total mass of SnPb solder in the above table is 5.095 tonnes. The solder used contains 37% lead by weight and so the mass of lead used in MMD sold in the EU annually is **1.9 tonnes**

It is estimated that the EU accounts for about a third of global MMD sales so the quantity of lead used globally is 5.7 tonnes of lead.