Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive)

Final report

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Excerpt of Final Report 2012

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11 Exemption request no. 8

“Lead in Solder for Electrical Circuitry that is used at Temperatures below -20°C”

COCIR (2011) requests an exemption for “Lead in Solder for Electrical Circuitry that is used at Temperatures below -20°C”.

Abbreviations

Ag	silver
Bi	bismuth
MEG	magneto-encephalography
MRI	magnetic resonance imaging
NMR	nuclear magnetic resonance
Pb	lead
Sn	tin
SQUID	superconducting quantum interference device

11.2 Description of requested exemption

COCIR (2011) explains that exemption 12 in RoHS Annex IV allows the use of “Lead and cadmium in metallic bonds to superconducting materials in Magnetic Resonance Imaging (MRI) and Superconducting Quantum Interference Device (SQUID) detectors”. This exemption covers electrically conducting bonds to the MRI superconducting magnet coil and to the SQUID detectors of MEG. Both of these products contain electrical circuits that are very cold but are not superconducting. This circuitry includes

- all of the electrical circuits that sustain the magnetic field,
- the safety shut down circuit,
- the magnet protection circuit,
- the helium monitoring circuit,
- the pressure monitoring and control circuit, etc.

According to COCIR (2012a), MRI magnets generating a magnetic field strength greater than a few tenths of a Tesla rely on superconducting wires (wires with zero electrical resistance) carrying electrical currents of a few hundred Amperes to generate the magnetic field. Use of non-superconducting wires would result in very high energy consumption and heat generation which would make the MRI magnet extremely costly and impractical. Superconducting wires only have zero electrical resistance at cryogenic temperatures. The actual temperature below which the wire has zero electrical resistance is dependent upon the wire material, operating current and magnetic field. Typical MRI magnets use NbTi superconductors, which must remain at a temperature below ~ 5 K (-268 °C) in order for the magnet to operate. Other superconducting materials do exist which can operate at higher temperatures. The only material available in commercial quantities is Nb_3Sn, which is technically more challenging to work with, significantly more expensive and is not superconducting above ~ 20 K (-253°C). So-called High Temperature Superconductors (HTS) are not expected to become cost competitive with NbTi and they are not produced in the quantities that the MRI industry requires. In addition, many technical challenges have to be overcome to enable their use in whole body MRI magnets and these HTS materials are still limited to operating at temperatures below ~150K (-83°C). No material exists which would allow whole body MRI magnets to operate at temperatures above -20°C.

Some solders are used in the coldest parts of some types of medical and other equipment such as an MRI machine that operates at 4 Kelvin (-269°C). There are several other types of equipment that utilise electrical circuits at very low temperatures including cyclotrons which are used to generate high energy particles and nuclear magnetic resonance (NMR) analysers, which are used for chemical analysis of organic substances. Both use superconducting magnets similar to those used for MRI. Cryogenic oxygen generators are used to make liquid oxygen for medical and other uses and will also have circuitry at low temperatures.

During normal operation, parts of the circuitry are thus exposed to a temperature range of 4 Kelvin to 100 Kelvin (respectively -269°C to -173°C). During ramp up of the magnet, the temperature range in parts of the circuitry can be approximately 100 Kelvin to 200 Kelvin (around -173°C to -73°C). During construction and under certain fault conditions this rises to room temperature values.

The solders used must be stable at these very low temperatures and tin-lead has traditionally been used as it is ductile and does not suffer from a destructive phase transformation known as “tin pest” during the normal life of these products.

COCIR (2011) says that this exemption is needed to allow the use of lead in tin-based solders, which are used, at least for part of their lifetimes, at temperatures below -20°C. COCIR (2012a) calculates the amount of lead used in this application as follows:

- The exemption would be used mainly in MRI systems, but also in NMR, MEG and in cyclotrons for particle therapy, all of which are also liquid helium cooled and have solder bonds under very low temperature conditions for the same reasons as MRI.

- Within the sealed vessel of MRI there are typically 2 to 3 PWB assemblies comprising approximately 100 joints per board. The MRI magnet also contains a number of small wire gauge cable looms which are comprised at one end of various sensors and devices that monitor and/or control the operation of the superconducting magnet, and which are exposed to the external world via hermetic connectors. This results in approximately 100 to 200 joints.
- The magnet also has main current leads (max current approximately 700 A) that are crimped and soldered to form the main current path for ramping up the superconducting magnet.
- The amount of lead per MRI may differ. One manufacturer calculated approximately 0.5 kg of lead per MRI magnet, another manufacturer indicated approximately 1.8 kg for 1.5 T magnets, 0.97 kg for 1.0 T, and 2.7 kg for 3.0T.
- According to COCIR (2012a) around 700 of such devices are sold worldwide, of them around 280 within the EU. This results in a total use of lead of around 450 kg worldwide and around 180 kg in the EU.

11.3 Applicant’s justification for the exemption

The most widely used lead-free solders are tin with silver and copper but it is well known that these alloys cannot be used at very low temperatures. This is due to “tin pest” where the tin undergoes a phase transformation from white “β” tin into grey “α” tin with an associated large change in volume (26%). This phase transformation causes the metal to disintegrate into a fine powder so that the electrical connection is lost. One recent example was of a laptop PC made with a tin/silver/copper solder alloy that was used in the mountains of Afghanistan by the US military. This failed after only a few years because the solder joints disintegrated as a result of the very low temperatures experienced in the field[16]. (COCIR 2011)

Tin pest occurs readily with pure tin and can, in theory, occur at temperatures below +13°C although it is not normally a serious problem with commercial lead-free solders at temperatures above -20°C. Some metal additives reduce the rate at which the phase transformation occurs and metals that dissolve in tin such as lead are effective to some extent.

It is therefore necessary to use lead in solders that are used below -20°C. There are no suitable alternative alloys that have the same or better resistance to tin pest and are known to provide high reliability at very low temperature conditions for the normal lifetimes of the equipment. High reliability is essential for certain types of medical devices such as MRI and

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[16] http://www.indium.com/images/blogs/drlasky/files/TinPestPaper0723Final.pdf, referenced in COCIR (2011)

MEG. Unexpected failures pose a risk to the health of patients as the devices are not available when diagnosis or treatment is needed. Electrical circuits used at low temperatures cannot be assembled without soldering with tin-based alloys as will be explained here.

11.3.1 Tin pest

Tin pest has been known for many decades, but most research has been carried out at temperatures between -50 and -30°C because the phase transformation occurs most rapidly within this temperature range. The rate of tin pest transformation depends on two distinct processes:

- The first is nucleation where minute α-phase particles are formed within the β-phase. The driving force for nucleation is the difference in temperature between 13°C and the actual temperature and so the driving force for nucleation increases as the temperature drops. Nucleation usually requires a defect such as a grain boundary or a particle of impurity but the time for nucleation to occur can vary considerably.
- The second process is phase transformation where the α-phase grows from the initial nucleation sites. The rate at which this occurs also varies considerably depending on the alloy composition and its history (as this affects crystal structure) as well as the temperature.

Past research results have been rather confusing due to very inconsistent results, believed to be due to variables that affect the rate at which nucleation occurs as well as the rate of phase transformation, neither of which were understood or adequately controlled. Low levels of impurities are now known to be important but in early research these were not accurately determined because analysis techniques of sufficient accuracy were not available. Other variables that affect rates of both nucleation and transformation include cold working, thermal history, rate of cooling of solder, aging of solder, the effect of creep, all of which have all been found to affect the rate of phase transformation, some to a considerable extent.

Research at the Open University by Plumbridge[17] showed that pre-treatment of solder samples in ways that real solder joints experience gives samples which had a much higher phase transformation rates than samples that were cast and slowly cooled. In the Open University research, tin pest nucleation was found to take many years with some alloys. After nucleation, transformation from white to grey tin occurs as the nucleated particles grow. The rate of phase transformation depends on temperature and as with most chemical and physical processes, this decreases as the temperature drops. The kinetics of tin pest is therefore very complex, but the net result is that the phase transformation is usually fastest between around minus 30°C and minus 50°C.

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[17] Plumbridge, W.J. “Further Observations on tin pest formation in solder alloys”, J. Electronic Materials, Vol. 39(4), p. 433, 2010, referenced in COCIR (2011)

Other elements added to tin significantly alter the tin pest behaviour. Some metals such as lead, antimony and bismuth retard tin pest whereas some such as copper and iron appear to increase the transformation rate. Metals that dissolve in tin such as lead usually retard tin pest as the solution of metals is less susceptible whereas metals such as copper that form solid inter-metallic phases increase the rate of transformation possibly due to the inter-metallic crystals acting as nucleation sites.

There is a lot of published research into tin pest, but frequently this provides contradictory results. It is believed that this is because tin pest transformation rates depend on all of the alloying elements including trace impurities present at very low concentrations which are usually not controlled. Research shows that high purity tin with intentional additions can give very fast phase transformations whereas commercial purity solders take much longer due to these trace impurities.

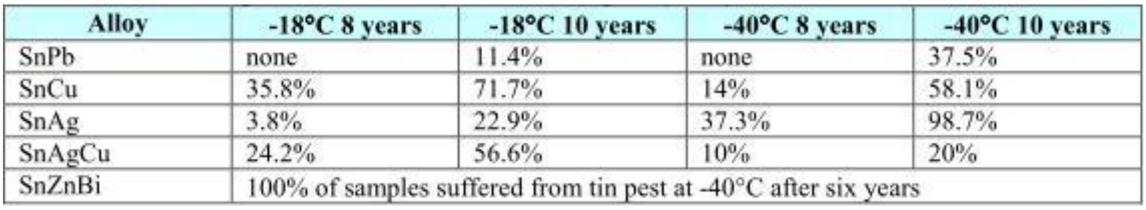
There are two other limitations with published research that is relevant to this exemption request. Firstly, most research is carried out over a period of less than two years (post graduate studies are usually completed with three years), but this is not sufficiently long to determine if and when tin pest will occur with commercial alloys because equipment lifetimes are much longer. Unlike other physical processes, it is not possible to artificially accelerate tin pest. Many physical processes are accelerated by raising the temperature but this is not possible for tin pest because if temperature is increased, nucleation is retarded and no transformation will occur if the temperature exceeds 13°C. Research therefore needs to be carried out for periods that are similar to the lives of the electrical products and for MRI. This can be 30 years. The other problem is the temperature at which research is carried out. The rate of phase transformation slows with decreasing temperature and so most research is carried out between around minus 30°C and minus 50°C to obtain results within the shortest time possible although this still takes many years.

The electronics located in cold regions of MRI are at temperatures as low as 4K which means that the rate of phase transformation will be slower than at minus 30°C and minus 50°C. However it is very difficult to determine by how much the rate is slowed and whether a solder alloy will survive 30 years based on research only at minus 30°C if there is no other data point at very low temperature to allow extrapolation.

Research published by the Open University has shown, after testing a range of commercial alloys at -18°C and -40°C for over 10 years, that some alloys such as SnCu suffer tin pest sooner at -18°C whereas others such as SnAg suffer tin pest sooner at -40°C. This research also showed that tin-lead solder also eventually suffers from tin pest at both temperatures although this alloy has been used in MRI for many decades without problems, which indicates that at the much lower temperatures, the rate is sufficiently reduced for the solder to survive the life of the MRI. However this cannot be certain for any other alloys, especially if they have been shown to suffer from tin pest more rapidly than tin-lead.

The Open University research is studying SnCu, SnAg, SnAgCu and SnZnBi. All alloys have been studied so far for over 10 years at both temperatures except for SnZnBi with only six years. Table 11 summarises the results.

Table 11: Tin pest in tin alloys (COCIR 2011)



Alloy	-18°C 8 years	-18°C 10 years	-40°C 8 years	-40°C 10 years
SnPb	none	11.4%	none	37.5%
SnCu	35.8%	71.7%	14%	58.1%
SnAg	3.8%	22.9%	37.3%	98.7%
SnAgCu	24.2%	56.6%	10%	20%
SnZnBi	100% of samples suffered from tin pest at -40°C after six years			

These results show that all of the substitute alloys tested suffer from tin pest much sooner than SnPb, especially the standard lead-free alloys that are now widely used by the electronics industry. This research also shows that a lead-free solder containing bismuth is also unsuitable as it suffered from tin pest after less than 6 years, much sooner than SnPb.

Evidence that bismuth is less effective than lead additions to tin coatings is also available from research published in 2009[18]. This describes a case study where electroplated tin connectors suffered from tin pest after low temperature storage. This investigation found that 5% lead addition was effective at preventing tin pest, but 0.5% bismuth or antimony were less effective. A 0.5% bismuth addition is fairly standard for coatings on connector terminals.

The Open University ten years' research is the only long-term work on tin pest at low temperatures. All other research is much shorter. Where this research showed no transformation, the results are of little value as phase transformation may take longer than the duration of the tests and no comparison with tin-lead can be made. Tin pest unlike other physical processes cannot be accelerated because cooling slows the transformation rate and heating up to just below 13°C drastically slows the nucleation rate. No transformation occurs at higher temperatures. For details about nucleation see exemption request 7, section 10.3.2.

COCIR (2011) explains that tin alloys used in MEG will experience much lower operating temperatures than the minus 45°C studied in the Open University research. The effect of temperature on tin pest is that with decreasing temperature the thermodynamic energy to cause the phase transformation increases, but the rate of physical processes decreases. It is therefore difficult to predict what might happen at much lower temperatures and very little

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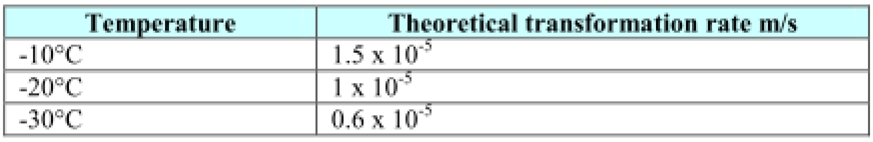
[18] Burns, N.D. "A tin pest failure", J. Failure Analysis and Prevention, Vol. 9(5), p. 461, 2009, referenced in COCIR (2011)

published research is available. The overall rate of transformation depends on both nucleation and transformation. Published research[19] has shown that transformation rates depend on the temperature as illustrated in Table 12.

Table 12: Transformation rates at different temperatures (COCIR 2011)



Temperature	Theoretical transformation rate m/s
-10°C	1.5×10^{-5}
-20°C	1×10^{-5}
-30°C	0.6×10^{-5}

Nucleation rates depend on many variables including alloy composition, cooling rate, work history, etc., as well as temperature. Overall tin pest failure rates are impossible to predict and so must be measured. (COCIR 2011)

Alloy composition is one factor and Plumbridge found that tin pest occurred more quickly with SnCu and SnAgCu at -18°C than at -40°C whereas SnAg and SnPb was more rapid at -40°C than at -18°C. These differences are probably due to differences in both nucleation and transformation rates at these two temperatures and therefore it is impossible to predict how long tin pest will take to occur with lead-free alloys at all of the wide range of temperatures that occur within MRI and MEG cryogenic systems.

Very little research with tin-bismuth solders at very low temperatures could be found except for the work described above that indicates that it will be inferior to tin-lead. The US standard ASTM B545 states that “where electroplated tin coatings are subject to long-term storage or use at very low temperatures, it may be advisable to co-deposit small amounts (<1%) of bismuth, antimony, or lead with the tin. These alloying additions, particularly the first, have been shown to inhibit the transformation”. Also, the US Federal specification QQ-S-571 recommends 0.27% antimony addition to tin to prevent tin pest. The only other possible alloy addition where some research has been carried out is with additions of antimony.

The research described above shows that very low concentrations of antimony are ineffective, but tin-antimony solders with several percent of antimony is described in a patent application for cryogenic pumps as being resistant to tin pest at temperatures as low as 4 K[20]. SnSb solder is also recommended for cryogenic use by Vishay[21]. This states that the “presence of antimony prevents “tin disease”, can be used in cryogenic environments,

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[19] http://www.electroiq.com/index/display/packaging-article-display.articles.advanced-packaging.volume-15.issue-11.features.tin-pest-in-tin-rich-solders.html, referenced in COCIR (2011)

[20] Patent Application WO/2009/146120 “Cryogenic pump employing tin-antimony alloys and methods of use”, D. Ball-Difazio, 2009; document referenced in COCIR (2011)

[21] Vishay “Solders and Accessories”, document number 1102319 th October 2004, referenced in COCIR (2011)

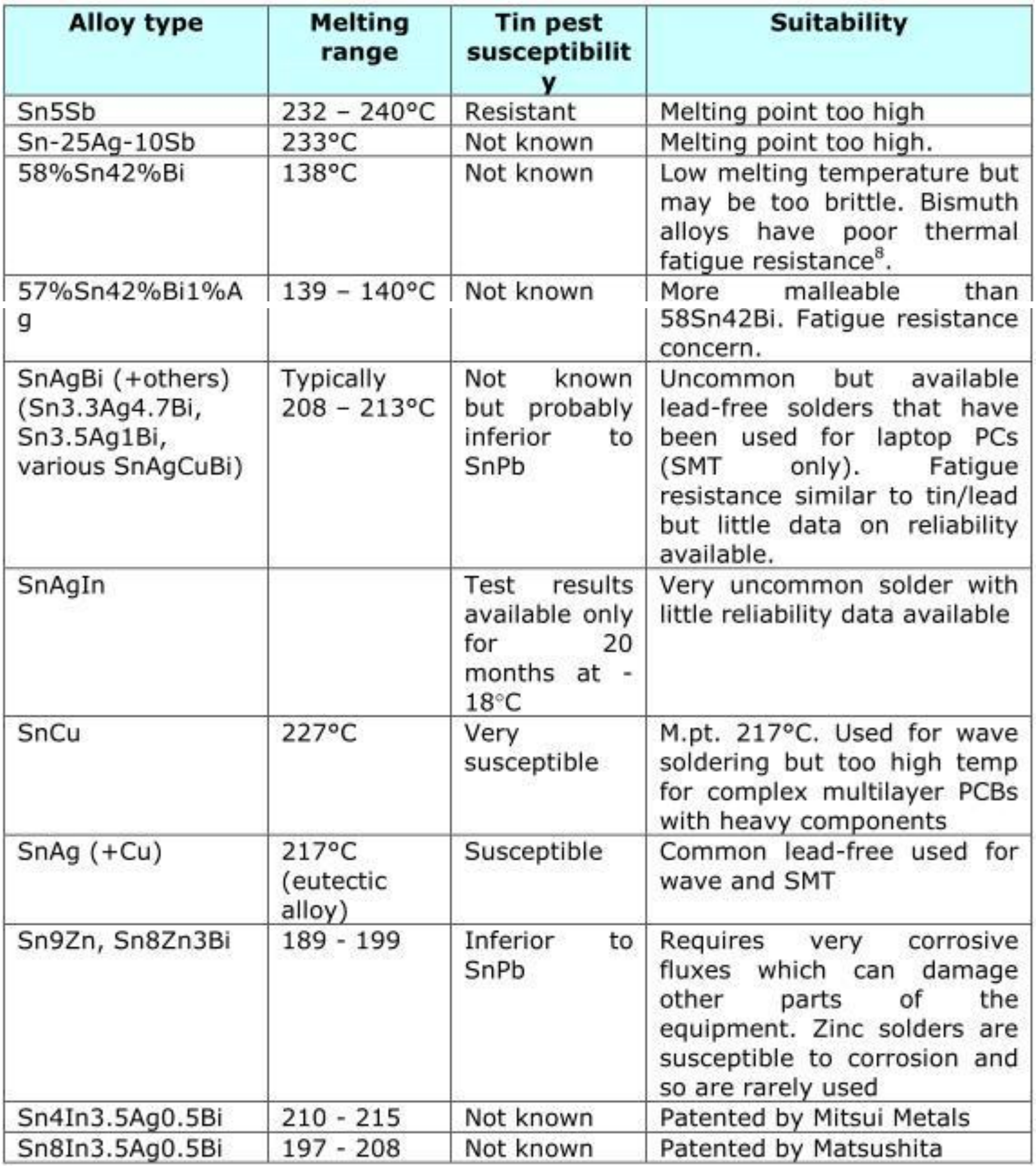
although is quite brittle at low temperature” and refers to the alloy with 5% antimony that has a melting temperature of 232–238°C. Sn5%Sb solder is therefore a very poor choice for MRI and MEG for two reasons:

- Its melting range of 232–238°C is 21°C hotter than standard SAC (SnAgCu) solder that melts at 217°C. The typical soldering temperature of SAC is ~260°C which is close to the upper safe limit for many types of electronic components. As 280°C would be needed for Sn5%Sb, this would be too hot for many types of electronic component and is likely to cause other types of defects to the printed circuit board that occur at very high temperature such as CAF (conductive anodic filaments) and board warping as well as destroying many types of component.
- Vishay states that Sn5%Sb is brittle at low temperatures. However there is considerable vibration in MRI machines and the cold electrical circuitry needs to withstand this severe vibration for the life of the equipment. The risk is high that Sn5%Sb would suffer from brittle failure due to this vibration.

11.3.2 Long term reliability of lead-free alloys at low temperatures

COCIR (2011) says that bismuth is used in some less common lead-free alloys but very little research on its low temperature properties has been published. SnSb solders are used as die attach alloys and to bond the pins of pin grid arrays to the IC package, but it is not used for assembling printed circuit boards as its melting point is too high. Table 13 gives an overview on the properties of lead-free alloys.

Table 13: Overview on properties of potential lead-free alloys (COCIR 2011)



Alloy type	Melting range	Tin pest susceptibility	Suitability
Sn5Sb	232 – 240°C	Resistant	Melting point too high
Sn-25Ag-10Sb	233°C	Not known	Melting point too high.
58%Sn42%Bi	138°C	Not known	Low melting temperature but may be too brittle. Bismuth alloys have poor thermal fatigue resistance[8].
57%Sn42%Bi1%Ag	139 – 140°C	Not known	More malleable than 58Sn42Bi. Fatigue resistance concern.
SnAgBi (+others) (Sn3.3Ag4.7Bi, Sn3.5Ag1Bi, various SnAgCuBi)	Typically 208 – 213°C	Not known but probably inferior to SnPb	Uncommon but available lead-free solders that have been used for laptop PCs (SMT only). Fatigue resistance similar to tin/lead but little data on reliability available.
SnAgIn		Test results available only for 20 months at -18°C	Very uncommon solder with little reliability data available
SnCu	227°C	Very susceptible	M.pt. 217°C. Used for wave soldering but too high temp for complex multilayer PCBs with heavy components
SnAg (+Cu)	217°C (eutectic alloy)	Susceptible	Common lead-free used for wave and SMT
Sn9Zn, Sn8Zn3Bi	189 - 199	Inferior to SnPb	Requires very corrosive fluxes which can damage other parts of the equipment. Zinc solders are susceptible to corrosion and so are rarely used
Sn4In3.5Ag0.5Bi	210 - 215	Not known	Patented by Mitsui Metals
Sn8In3.5Ag0.5Bi	197 - 208	Not known	Patented by Matsushita

HP tested 58%BiSn versus 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all of the package types tested.[22]

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[22] "Low-temperature Solders", Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996, referenced in COCIR (2011)

11.3.3 Other issues with lead-free solders at low temperature

COCIR (2011) argues that most research with lead-free solders has been carried out to simulate and accelerate the conditions experienced by consumer, household and IT products although some military-type applications have also been considered. Some of the tests involve brief excursions below 0°C (down to -40°C) but the time at low temperature in total is always relatively short and almost no research has been carried out at the temperatures that exist in cryogenic MRI and MEG applications.

COCIR (2011) concludes that apart from the risk of tin pest, the long term reliability of lead-free solder joints at very low temperatures is not known. Solders become less ductile as the temperature decreases and so at very low temperature they can become very brittle. Lead-free solders are less ductile than tin-lead solders at room temperature, as the Vickers hardness indicates:

▪ Eutectic tin 37% lead	Vickers hardness = 12.9
▪ Tin 4.7% silver 0.7% copper	Vickers hardness = 21.9

COCIR (2011) references research showing that lead-free solders are more susceptible to failure than eutectic tin lead solders when exposed to vibration with high g-forces[23]. The MRI environment is very harsh compared to other industries. The interaction of the strong magnet and gradient field can cause vibration and temperature fluctuations which can have detrimental effects on solder joints. Vibration and temperature cycling typical of consumer and IT equipment has been extensively studied, but there has been no research carried at the low temperatures that occur close to MRI magnets.

COCIR (2012a) argues that MR scanners are expected to be in service with clients for at least 10 years. To simulate actual vibration levels and thermo-mechanical effects for at least 10 years service, the typical test conditions used for MR environment reliability tests are:

- Vibration levels up to 70 G_{rms} for 180 hours, corresponding to 19,000 hours MRI scan time, which, according to COCIR (2012a), is far worse than automotive.
- Number of temperature Cycles (=number of exams on patients) is 6300/year covering 90% of MRI used in the EU. This is, according to COCIR (2012a), far worse than automotive, and comparable with space.

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[23] Various research studies, e.g. http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/JTR%20Reliability%20Conclusions%20March%2028%202006.pdf, referenced in COCIR (2011)

> COCIR (2011) concludes that there is therefore an unquantifiable risk that lead-free solders, which are brittle at low temperatures, have a greater risk of failure at very low temperatures due to vibration than more ductile tin-lead solders.

11.3.4 Alternative bonding materials and techniques

COCIR (2011) provide some details about possible alternatives for bonding materials and techniques.

Solder alloys with lead contents below 0.1% of weight

Medical equipment manufacturers have to use commercially available solders and so solder with slightly less than 0.1% lead cannot be easily obtained. The lead content of lead-free commercial solder does, however, vary. Alloys with 0.08% of lead may be found although alloys with 0.03% to 0.05% lead are more common. It is likely that 0.08% lead will give some improved resistance to tin pest compared to no lead, but the resistance is unlikely to be sufficient.

Eutectic SnPb solder contains 37% lead, far more than 0.08%. The Open University research described above used commercial lead-free solder alloys which will contain less than 0.1% of lead, probably around 0.05% as this is typical. This concentration of lead is clearly insufficient and so more than 0.1% lead is needed.

Conductive adhesives as alternatives to solders

An alternative to solders are conducting adhesives. This is, however, only very rarely used to assemble electrical circuitry because its long term reliability and performance (i.e. permanent low electrical resistance) is usually inadequate for most applications. It will not be suitable for use in this application because the bonds to components must be resistant to severe vibration and large temperature changes including very low temperatures where most adhesives will become extremely brittle.

Brazing and welding

Brazing and welding avoids the use of tin so that tin pest is not an issue. However, these bonding techniques cannot be used to build electrical circuitry between copper wire and electronic components because the very high temperatures of more than 500°C for brazing and more than 1,000°C for welding would destroy not just many of the types of components that need to be used, but also the printed circuit board material on which they are to be mounted.

11.3.5 Environmental and resource aspects

Even though no technically viable substitute has been identified at present, COCIR (2011) have submitted further information concerning life cycle aspects, of potential substitutes (bismuth / indium / antimony / silver / zinc) to further enhance their argumentation.

Information includes reference to the availability of other metals, the energy consumption required for their extraction and refining and information concerning the re-use and recycling of waste.

11.3.6 Roadmap for the substitution of lead

Research into lead-free solder alloys for use at low temperatures

It is necessary to gain approvals under the Medical Device Directive after a change has been made to a medical product before the modified product design can be sold in the EU. The change from SnPb solder to lead-free solder is sufficient to require extensive testing and application for approval.

The most time consuming research however is the search for tin pest resistant solders that are suitable for use in MRI, MEG, etc. Research described above shows that at least 10 years testing of potential solders at realistic temperatures for these applications will be needed and this cannot be accelerated. Work published to date has not identified a suitable lead-free alloy and so alternative alloys will need to be evaluated. If this were to begin in 2011, it would not be completed until at least 2021, and ideally longer testing should be carried out.

If a potentially suitable alloy were to be identified, time would be required subsequently to:

- Construct prototype circuit board assemblies and carry out comprehensive reliability testing, which can take two years.
- Build prototype equipment such as MRI using the new alloy (if identified by testing described above) and carry out extensive testing to ensure that accuracy of results and long term reliability are not affected. This can take another two years
- Submit reliability data to Notified Body and request MDD approval. MRI and MEG are complex products so that this could take another year.

These activities will require a further five years after tin pest testing which means that this exemption would be required until at least 2026 with 2030 being realistic, although it is possible that no suitable substitutes will be identified for this very demanding application.

COCIR (2011) concludes that it will clearly be impossible to replace tin-lead with an alternative solder in the period remaining before medical devices are included in the scope of the RoHS Directive and therefore asks for an exemption to be included in Annex IV of the RoHS Directive.

11.4 Critical review

11.4.1 Relation to the REACH regulation

Chapter 5 of this report lists entry 30 restricting the use of lead and its compounds in Annex XVII and the related authorization and restriction processes in the REACH Regulation. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants' understanding, entry 30 of Annex XVII does not apply to the use of lead in solders and termination coatings. Lead and the tin-lead alloy used may be considered as substance, as constituent of another substance or a mixture. Putting, however, lead in solders and finishes on the market in the reviewers' point of view is not a supply of lead and its compounds to the general public. Lead is part of an article and as such not covered by entry 30 of Annex XVII.

The consultants conclude that the use of lead in this requested exemption does not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

11.4.2 Scientific and technical practicability of substitution and elimination of lead

The applicant was asked whether it was not possible to install the printed circuit boards outside the cold zone thus avoiding the tin pest and potential reliability implications at low temperatures. COCIR (2012a) explains that for its operation a superconducting magnet relies on cryogenic. For the control and monitoring of the superconducting magnet, various sensors and devices are exposed to very low temperatures. The magnet would not work without these devices, and a number of these devices are integral to the safety of the magnet system e.g. ensuring uncontrolled high voltages do not appear externally during fault conditions, or that the magnet can be brought to zero field in the event of an emergency.

Furthermore, COCIR (2012a) puts forward that the number of connections between the cryogenic parts of the magnet and the external world (at room temperature) is as small as possible to minimize cooling needs and respectfully, energy consumption and to avoid loss of liquid helium. The connections to each sensor and to the superconducting coil therefore are within the cryogenic sealed vessel which is operated at low temperatures. Solder connections are the only type that will be reliable at such low temperatures. Sensors and other devices are not made with very long leads and if they were, these could not be passed through the wall of the sealed vessel.

There is thus no information showing that the substitution or elimination of lead is possible in this application.

11.4.3 Environmental arguments

The applicant puts forward environmental data and statements comparing the life cycles of lead with potential substitutes. As none of the substitutes can actually be used currently, these arguments were not reviewed. The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments

11.4.4 Conclusions

The applicant's scientific and technical arguments put forward for the justification of the exemption request are plausible. In the absence of contrary information, the consultants conclude that the substitution or elimination of lead is currently not possible in this application.

COCIR puts forward that little research has been conducted on such extreme low temperature applications of tin-based lead-free alloys. It is not clear whether research into viable substitutes actually would take until 2026 however as demonstrated by the applicant, it is clear that besides the time required for research into substitutions, additional time would be required to complete the authorization of use of substitutes in these applications due to their medical purpose.

It was finally and officially clear in July 2011 – the date of publication of the new RoHS Directive – that the devices of category 8 (medical equipment) of RoHS Annex I will come into the scope of the RoHS Directive, which in the consultants' point of view is the latest point in time when the manufacturers had been expected to start their research and substitution efforts. Thus, with less than one year passed since the adoption of category 8 into the scope of the RoHS Directive, in the absence of substitution and elimination possibilities, and in light of the additional time required for reliability testing and qualification of lead-free solutions, the consultants have no indication to recommend an expiry date prior to the seven years maximum validity of exemptions adopted to Annex IV.

To clarify the scope of the exemption, the following wording was agreed with COCIR (2012c):

Lead in

- solders on printed circuit boards,
- termination coatings of electrical and electronic components and coatings of printed circuit boards
- solders for connecting wires and cables,
- solders connecting transducers and sensors,

that are used durably at a temperature below –20°C under normal operating and storage conditions.

11.5 Recommendation

Based on the documents submitted by the stakeholders and in the absence of contrary information, the requested exemption would be in line with the requirements of Art. 5(1)(a). The consultants therefore recommend adding an exemption to Annex IV of the RoHS Directive with the following wording:

> *Lead in*
>
> - *solders on printed circuit boards,*
> - *termination coatings of electrical and electronic components and coatings of printed circuit boards*
> - *solders for connecting wires and cables,*
> - *solders connecting transducers and sensors,*
>
> *that are used durably at a temperature below –20°C under normal operating and storage conditions.*

The consultants recommend not to set an expiry date prior to the end of the maximum validity period of the exemption in July 2021.

11.6 Specific references

COCIR 2011	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Original exemption request document "8-COCIR – Exemption request – Lead in solders low temperature.pdf"; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_8/8_COCIR_-_Exemption_request_-_Lead_in_solders_low_temperature.pdf
COCIR 2012a	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Questionnaire1_Exe-6_-answers_rev.pdf" submitted by stakeholder on exemption request no. 6 for the stakeholder consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_8/Questionnaire-1_Exe-8_answers.pdf
COCIR 2012b	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document:

	Questionnaire-2_Req-8 Answers.doc", submitted by stakeholder on exemption request no. 8 on 9 May 2012
COCIR 2012c	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR): Stakeholder document "Final clarifications.pdf", submitted by stakeholder on exemption requests 7, 8, 9 and 10 on 31 May 2012
Deubzer 2007	DEUBZER, Otmar: Explorative Study into the Sustainable Use and Substitution of Soldering Metals in Electronics – Ecological and Economical Consequences of the Ban of Lead in Electronics and Lessons to Be Learned for the Future; PhD thesis TU Delft, The Netherlands, January 2006, ISBN 978-90-5155-031-3, http://repository.tudelft.nl/view/ir/uuid%3Af9a776cf-57c3-4815-a989-fe89ed59046e/
Gensch et al. 2006	Gensch, C.; Zangl, S.; Möller, M.; Lohse, J.; Müller, J.; Schischke, K.; Deubzer, O. Adaptation to Scientific and Technical Progress under Directive 2002/95/EC, Final Report, Öko-Institut e.V. and Fraunhofer IZM, July 2006; http://ec.europa.eu/environment/waste/weee/pdf/rohs_report.pdf.
Gensch et al. 2007	Gensch, C.; Zangl, S.; Deubzer, O. Adaptation to Scientific and Technical Progress under Directive 2002/95/EC, Final Report, Öko-Institut e.V. and Fraunhofer IZM, October 2007; http://rohs.exemptions.oeko.info/fileadmin/user_upload/rohs_final_report_Oeko_Institut__22-Oct-2007_01.pdf
Gensch et al. 2009	Gensch, C.; Zangl, S.; Groß, R.; Weber, A. K.; Deubzer, O.; Adaptation to scientific and technical progress under Directive 2002/95/EC; Final Report, Öko-Institut e.V. and Fraunhofer IZM, February 2009; http://ec.europa.eu/environment/waste/weee/pdf/report_2009.pdf
Goodman 2006	Goodman, P. Review of Directive 2002/95/EC (RoHS) categories 8 and 9 – Final Report. ERA Report 2006-0383, July 2006, amended September 2006; http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf
Goodman 2009	Goodman, P. Additional Exemptions from the RoHS Directive needed by the Medical Industry. ERA Report on behalf of COCIR, September 2009; http://www.cocir.org/uploads/documents/38-1248-8-1100-cobham_era_report_on_rohs_exemptions_for_medical_devices_sept_2009.pdf
RoHS Directive 2003	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0095:EN:NOT

RoHS Directive 2011	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); http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT
Zangl et al. 2010	Zangl, S.; Hendel, M.; Blepp, M.; Liu, R.; Gensch, C.; Deubzer, O. Adaptation to scientific and technical process of Annex II to Directive 2000/53/EC (ELV) and of the Annex to Directive 2002/95/EC (RoHS); Final Report, Öko-Institut e.V. and Fraunhofer IZM, June 2010; http://circa.europa.eu/Public/irc/env/elv_4/library?l=/reports/final_rohs_2010pdf/_EN_1.0_&a=d
Zangl et al. 2011	Zangl, S.; Blepp, M.; Lui, R.; Moch, K.; Deubzer, O. Adaptation to Scientific and Technical Progress under Directive 2002/95/EC – Evaluation of New Requests for Exemptions and/or Review of Existing Exemptions, Final Report, Öko-Institut e.V. and Fraunhofer IZM, May 2011; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IV/RoHS_final_report_May_2011_final.pdf

12 Exemption request no. 9

“Lead in solders and solderable coatings used on non-magnetic components and circuits that are used in magnetic fields or are associated with circuits used inside strong magnetic fields”

Abbreviation

G_{rms}	unit to specify and compare the energy in repetitive shock vibration systems[24]

12.2 Description of requested exemption

Magnetic Resonance Imaging (MRI), high-end Nuclear Magnetic Resonance (NMR) analysis and cyclotrons for particle therapy utilise very powerful magnets. MRI is a medical technique used to diagnose conditions associated with soft tissue such as detecting tumours,

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[24] Doertenbach, Neill, QualMark Corp.: The Calculation of G_{rms}; http://www.dfrsolutions.com/uploads/services/HALT_grms_calculation_ndoertenbach.pdf; last accessed 23 April 2012