

## Application for granting new Exemption: Lead in solder for electrical circuitry that is used at temperatures below -20°C

## 1. Name and address of applicant

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## 2. Summary of the application

Several medical and analytical techniques utilise electrical circuitry at very low temperatures. An exemption is needed to allow the use of solders containing lead because these alloys are the only types known to survive the normal expected lifetime of medical devices such as MRI and also analytical instruments that utilise electrical circuits operating at very low temperatures. All tin alloys that can be used as solders undergo a phase transformation at low temperature that destroys solder bonds. Some metal additions retard the phase transformation but research has shown that none are as effective as lead. All of the lead-free solders that are currently available will transform at a faster rate so that products will have a shorter lifetime.

# 3. Description of materials and equipment for which the exemption is required

Exemption 12 in Annex IV of the recast RoHS Directive, "lead and cadmium in metallic bonds to superconducting materials in Magnetic Resonance Imaging (MRI) and Superconducting Quantum Interference Device (SQUID) detectors", covers electrically conducting bonds to the MRI superconducting magnet coil and to the SQUID detectors of MEG. Within both of these products are associated 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. 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 is 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.

The solders used must be stable at 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. Usually, these solder connections are produced by hand soldering and this ranges from bonds to fine signal wires to very thick high current cables. 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 " $\beta$ " tin into grey " $\alpha$ " 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 to 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 field1. 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.

This exemption is needed to allow the use of lead in tin-based solders that are used, at least for part of their lives at temperatures below -20°C.

## 4. Justification for exemption - Article 5 criteria

It is necessary to use lead in solders that are used below -20°C because 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 MEG as unexpected failures pose a risk to the health of patients as a result of these not being available when diagnosis or treatment are needed. Electrical circuits used at low temperatures cannot be assembled without soldering with tin-based alloys as will be explained here.

## 5. Analysis of possible alternatives

#### 5.1. Alternative solders - Possible allovs - tin pest resistance

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 occurring:

- The first is nucleation where minute  $\alpha$ -phase particles are formed within the  $\beta$ -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 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  $\alpha$ -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

<sup>&</sup>lt;sup>1</sup> http://www.indium.com/images/blogs/drlasky/files/TinPestPaper0723Final.pdf



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<sup>2</sup> showed that pretreatment 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 are therefore very complex but the net result is that the phase transformation is usually fastest between  $\sim\!-30$  and  $-50^{\circ}\mathrm{C}$ . 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 research into tin pest published 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 with 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 with commercial alloys to determine if and when tin pest will occur 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 decreases temperature and so most research is carried out between ~-30 and -50°C to obtain results in as short a time as possible (although this still takes many years). The electronics used in cold regions of MRI is at temperatures as low as 4K which means that the rate of phase transformation will be slower than at -30 and -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

 $<sup>^2</sup>$  W. J. Plumbridge, "Further Observations on tin pest formation in solder alloys", J. Electronic Materials, Vol 39 (4), p 433, 2010.



at  $\sim$ -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 which has results published after only six years. This research is summarised below. This includes data for what are referred to as "tested" samples. These are alloys that are treated to simulate the effects on real solder joints and so are more realistic than the untested samples. Alloys were cast with three different cooling rates and the most realistic, fast cooling showed the most likelihood of phase transformation but all samples are included in the table below which shows the percentage of samples that show more serious signs of phase transformation:

| Alloy  | -18°C 8   | -18°C 10 | -40°C 8 | -40°C 10 |
|--------|---|----------|---------|----------|
|        | years   | years    | years   | 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 possible substitute alloys suffer from tin pest much sooner than SnPb, especially the standard lead-free solders 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.

Research published in 2005 by a Japanese solder manufacturer found the following percentages of transformation at  $-45^{\circ}\text{C}^{3}$ .

| Additive to 99.99% tin | % of samples exhibiting phase transformation |                |  |
|------------------------|--|----------------|--|
|                        | After 10 hours                               | After 30 hours |  |
| Tin only               | 80%  | 100%           |  |
| 0.01%Sb                | 100%   | 100%           |  |
| 0.01%Cu                | 100%   | 100%           |  |
| 0.01%Zn                | 100%   | 100%           |  |
| 0.01%Ag                | 5%   | 78%            |  |

 $<sup>^{\</sup>rm 3}$  "Suppression of Tin Pest in Lead-free Solders" by Keith Sweatman, JEDEX conference, San Jose, USA 2005



| 0.01%Bi | 0.5% | 3.0% |
|---------|------|------|
| 0.01%Pb | 0%   | 0%   |

These results confirm that copper accelerates the transformation whereas silver delays but does not prevent transformation. It is often claimed that antimony can suppress tin pest but these results show that small additions are ineffective. Apart from lead, 0.01% bismuth had the greatest delaying effect but even after only 30 hours, 3% had transformed so that after sufficient time, the transformation would be complete. Lead was the most effective with no phase transformation being observed in this test. Further evidence that bismuth is less effective than lead is from research published in 2009 that 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<sup>4</sup>.

Solders in MRI and MEG however experience much lower operating temperatures than -45°C, although a wide range of temperatures occur. The effect of temperature on tin pest is that as this decreases, the thermodynamic energy to cause the phase transformation increases but the rate of physical processes decreases with temperature. It is therefore difficult to predict what might happen at much lower temperatures and very little published research is available. The overall rate of transformation depends on both nucleation and transformation. Published research has shown that transformation rates depend on the temperature<sup>5</sup> as shown in the table below:

| Temperature | Theoretical transformation rate m/s |
|-------------|-------------------------------------|
| -10°C       | 1.5 x 10 <sup>-5</sup>              |
| -20°C       | 1 x 10 <sup>-5</sup>                |
| -30°C       | 0.6 x 10 <sup>-5</sup>              |

Nucleation rates depend on many variables including alloy composition, cooling rate, work history, etc. as well as temperature and so overall tin pest failure rates are impossible to predict. 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

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<sup>&</sup>lt;sup>4</sup> N. D. Burns, "A tin pest failure", J. Failure Analysis and Prevention, Vol 9 (5), p 461, 2009

<sup>&</sup>lt;sup>5</sup>http://www.electroiq.com/index/display/packaging-article-display.articles.advanced-packaging.volume-15.issue-11.features.tin-pest-in-tin-rich-solders.html



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 4K<sup>6</sup>. SnSb solder is also recommended for cryogenic use by Vishay<sup>7</sup>. This states that the "presence of antimony prevents "tin disease", can be used in cryogenic environments, 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 PCB 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.
  There is therefore a high risk therefore that Sn5%Sb would suffer from
  brittle failure due to this vibration

## **5.2.** Alternative alloys – long term reliability at low temperatures

Bismuth is used in some less common lead-free alloys but very little research on its low temperature properties have 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.

Alternative alloys are summarised below:

| Alloy type    | Melting<br>range | Tin pest<br>susceptibilit<br>v | 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 <sup>8</sup> . |
| 57%Sn42%Bi1%A | 139 - 140°C      | Not known                      | More malleable than  |

<sup>&</sup>lt;sup>6</sup> Patent Application WO/2009/146120 "Cryogenic pump employing tin-antimony alloys and methods of use", D. Ball-Difazio, 2009

<sup>&</sup>lt;sup>7</sup> Vishay "Solders and Accessories", document number 1102319<sup>th</sup> October 2004.

<sup>&</sup>lt;sup>8</sup> HP tested 58%BiSn with 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all of the package types tested. "Low-Temperatre Solders", Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996.



| g  |                              |   | 58Sn42Bi. Fatigue resistance concern.  |
|--|------------------------------|---|--|
| SnAgBi (+others)<br>(Sn3.3Ag4.7Bi,<br>Sn3.5Ag1Bi,<br>various SnAgCuBi) | Typically<br>208 - 213°C     | Not known<br>but probably<br>inferior to<br>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 | ,  |
| SnCu   | 227°C                        | Very<br>susceptible                                 | M.pt. 217°C. Used for wave soldering but too high temp for complex multilayer PCBs with heavy components   |
| SnAg (+Cu)   | 217°C<br>(eutectic<br>alloy) | Susceptible   | Common lead-free used for wave and SMT   |
| Sn9Zn, Sn8Zn3Bi  | 189 - 199                    | Inferior to<br>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   |

## 5.3. Other issues with lead-free solders at low temperature

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. So 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 at room temperature, examples for unannealed alloys are:

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

MRI machines can experience vibration and temperature fluctuations and these 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. Research has shown that lead-free solders are more susceptible to failure than eutectic tin lead solders when exposed to vibration with high g-



forces9. There is therefore an unquantifiable risk that lead-free solders that will be very brittle at low temperature, have a greater risk of failure at very low temperature due to vibration than more ductile tin/lead solders.

## 5.4. Solder alloys with lead present at slightly below 0.1%

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 and alloys with 0.08% lead may be found although 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 <0.1% lead and probably ~0.05% as this is typical. This concentration of lead is clearly insufficient and so more than 0.1% lead is needed.

#### 5.5. Alternatives to solder

#### **Conducting adhesives**

An alternative to solders is 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 (>500°C for brazing and >1000°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.

#### 6. Life cycle assessment

**Lead** is mined in large quantities as a primary metal with about 8 million tonnes per year being produced. Consumption world-wide is increasing despite the RoHS restrictions due to its main uses for batteries and as a building material. The extraction and refining of lead from its ores is a well controlled process in most countries so that lead pollution does not occur. Sulphur dioxide is produced as a by-product which is used to make sulphuric acid. Lead solders can be recycled efficiently and safely using modern recycling technology.

## Alternative solder additions to lead:

Apart from tin which is used in all types of solder, the following metals have been considered as potential substitutes for lead.

**Bismuth** arises as a by-product from mining other metals including lead. It is a relatively rare metal occurring at low concentrations so that significant resources (i.e. energy and chemicals consumption) is required for its extraction and

http://www.jqpp.com/projects/lead free soldering/April 4 Exec Sum Presentations/JTR %20Reliability%20Conclusions%20March%2028%202006.pdf

<sup>&</sup>lt;sup>9</sup> Various research studies, e.g.



refining. Availability is not an issue, bismuth is not toxic and it is used in a variety of medicines.

Bismuth present in electronic circuit board waste interferes with the recycling process. At end of life, first the PCBs are removed from equipment (as required by the WEEE directive) and smelted to produce impure copper metal containing dissolved gold, silver, palladium, antimony, bismuth and other metals.

The crude copper is purified by electrorefining and precious metals, in particular gold are then recovered from the residue (the anode slime). If bismuth is present, this combines with precious metals in the slimes and requires an additional refining stage to separate it from gold and other metals.

**Indium** arises as a by-product from extraction of other metals and occurs at very low concentrations and so significant quantities of energy are required to extract and refine this metal. Availability is very limited with demand equal to or exceeding supply with most being used to manufacture displays. Demand for indium has increased significantly in recent years with supplies severely limited. Indium is not regarded as being hazardous although it is toxic if injected into the bloodstream.

Despite its high value, it is rarely recovered from scrap electronics, including from LCDs (its primary use) where it is used as a thin transparent coating.

**Antimony** – Antimony occurs mainly as sulphide ores such as "stibnite" and relatively small amounts occur as oxidic ores. Antimony sulphide is first concentrated and then heated under controlled conditions to produce antimony metal and sulphur dioxide which is recovered as sulphuric acid. This process is similar to the one used to refine lead from lead sulphide ores. The toxicity of antimony has been the subject of debate in recent years. Organic antimony compounds are very toxic but antimony metal and its oxide are very insoluble in both water and in stomach acid. There is no doubt that antimony poses a low health risk.

At end of life, antimony is not recovered from waste electronics because it is present at very low concentrations and has a very low value. It therefore may be emitted into the environment or occur with landfill waste.

**Silver** - Silver is widely distributed but occurs at low concentrations in a variety of ores and is usually recovered as a by-product. Extraction of silver ores involves mining very large quantities of rock which has very high energy consumption and generates very large amounts of waste. Refining is usually carried out using highly toxic cyanides and accidents have occurred which have caused very serious damage to the environment. More energy is required for soldering tin/silver solders due to the higher melting point than tin/lead. At end of life, silver is recovered due to its high value although in countries where unsafe recycling is carried out, environmental and health damage due to the use of cyanide is a significant risk. The United States Environmental Protection Agency carried out a comprehensive life cycle assessment comparing tin/lead with lead-free alloys including alloys containing silver<sup>10</sup>. This concluded that for the majority of environmental impacts, lead-free solders had greater negative impacts than the tin/lead solder they replace.

**Zinc** is also mined in very large quantities as a sulphide ore. As with lead, smelting zinc ores releases sulphur dioxide which is recovered as sulphuric acid. Although zinc itself has a relatively low toxicity, its ores often contain cadmium which can be separated but it is often left with the zinc if it is at concentrations below 100 ppm (the RoHS limit for cadmium in homogeneous materials). During all high temperature processes including smelting, some of this cadmium may

http://www.epa.gov/dfe/pubs/solder/lca/index.htm



volatilise to generate toxic emissions. At end of life, zinc is not usually recovered from printed circuit board scrap due to its reactivity and low value and so occurs in waste by-products.

## 7. Re-use and recycling of materials from waste EEE

Equipment such as MRI and MEG that contains electrical circuitry made with solders containing lead will be recycled when it reaches end of life. These types of equipment have high metals content and so its value makes recycling an attractive option. The first stage of the recycling processes is the removal of printed circuit boards. This is required by Directive 2002/96/EC Annex II but is carried out as this increases the efficiency of metals recovery from the PCBs as well as other parts of MRI, etc. Recycling of circuitry containing lead solders is a well established process with very high yields of metals including lead which is reused. The most efficient process to recover lead and other metals that should be used is smelting and there are several suitable well-controlled facilities in the EU. Smelting melts some metals, in particular copper and converts other metals such as lead and tin into their oxides which are collected and then usually first separated chemically before converting into metals.

Unsafe recycling of WEEE is carried out in some developing countries but this is mostly with IT, telecom and consumer equipment. Waste equipment from categories 8 and 9 is very unlikely to be recycled except by professional recyclers using well controlled safe processes.

## 8. Other information

It is estimated that  $\sim\!450$  kg of lead will be used in the EU annually for this application.

## 9. Proposed plan to develop substitutes and timetable

## Research into alternative solder alloys at very 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 and if this were to begin in 2011, it would not be complete 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, this 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.

It will clearly not be possible to replace tin/lead by an alternative solder before medical devices are included in the scope of RoHS.

## 10. Proposed wording for exemption

Lead in solder for electrical circuitry that is used at temperatures below - 20°C

This exemption can be included in Annex IV of Directive 2011/65/EC as it will be utilised only by category 8 and 9 equipment.