



## **Joint Industry contribution to the ÖKO Institute's consultation on the Actual Exemptions from the RoHS Directive**

**Brussels, April 1, 2008**

The signing Associations represents European manufacturers of medical devices and are most happy to contribute to the consultation on the actual exemptions from the RoHS Directive that will support the study the ÖKO Institute is doing for the European Commission. We are very committed to the objectives of the initiative and despite limited time we have tried to compile a list of those exemptions that are most critical to our sector and given examples of medical applications where they are needed.

The Category 8 is today not in the scope of the RoHS Directive, but the review of the Directive is considering including it. If the conclusion of this review is that Category 8 should be under the scope of the RoHS Directive, a number of additional exemptions will be needed in order to ensure continued access to today's healthcare. Our industries has already submitted an input on this question, based inter alia on the outcome of the ERA report '*Review of the Directive 2002/95/EC (RoHS) Categories 8 and 9*', 2006.

The present consultation is addressing existing exemptions and we fully realize there is a certain overlap between some of these and the exemptions we have already addressed.

The attached table indicates the most important applications of medical devices that today use RoHS substances in applications that are exempted from the scope of RoHS. As you will see many of them are critical to adequate functioning of the device. Often the total quantities are not known by our industry and in most cases we do not know when/if adequately validated alternatives with same characteristics will be available to our applications. For these details we refer to the ERA report. Concerning the exemption number 13, we are happy to refer to the contribution submitted separately by The European Optical Stakeholders (Spectaris et al)

We remains committed to do its best to provide any further information you may need on these applications and we are most willing to discuss any further exemptions needed.

## Annex

### Overview and Rationale of Actual RoHS Exemptions critical for Medical Devices Applications

#### Short explanation of each column

**Substance**

Usage of any restricted substance(s) listed in the RoHS directive.

**Typical Application and Approximate amount per product**

Function or part of a medical device in which the substance is applied and the amount of each Substance used.

**Total Weight of the substance put on the EU market in kg/Year**

Information in this column is derived from approximate units of Modalities marketed in the EU per year supplied by all manufacturers worldwide and the amount of Substance used by each Modality.

**Benefit**

Benefits, including medical, for using the Substance(s) in a Modality.

**Replace**

Lists any viable alternative to the restricted Substance. When considering this both technical alternatives and their associated financial implications are considered.

**Rationale**

This column gives the rationale for the continued use of a Substance as listed in the RoHS directive by a Modality.

## Overview and Rationale of Actual RoHS Exemptions critical for Medical Devices Applications

Exemption	Substance	Typical Application	Weight put on the EU market	Benefit	Replace	Rationale
3	Mercury	LCD Display screens backlight for Patient Monitoring and touch screens	A few grams per LCD	Superior customer/user interface and clarity of diagnostic information	Possible dependant on suppliers, by LED technology	Used in backlights. There is no industry alternative that can provide the same performance. Currently the mercury levels are very low.
5	Lead	X-Ray tube glass envelope	500 kg	Glass used as vacuum adhesive	No	Glass containing PbO is used as adhesive between the different glass and the metal ring. PbO serves to make the expansion coefficient of different glass correspond to that of the metal ring, enabling firm adhesion between the two to maintain a high level of vacuum without causing any mechanical strain. No other material to replace PbO in glass exists in an industrial and/or commercial scale at present.
6	Lead as Alloy material		5000 kg	Improve material properties	No	E.g. in aluminum, steel and bronze bearing alloys. Used to improve machinability (more than 0.4%). Specifically in aluminum about needs 5% to be used for machinability. Note, this is higher than the actual exemption.

Exemption	Substance	Typical Application	Weight put on the EU market	Benefit	Replace	Rationale
7	Lead in electronic ceramic parts	Ultrasonic Surgical Devices for therapeutic applications. (piezoelectric ceramics/ ultrasonic transducers).	100 Kg	Lead zirconate titanate (PZT) piezoelectric ceramics are used inside the ultrasonic transducer assemblies (conversion of electrical energy into mechanical energy). Optimal electromechanical behavior with > 50 years of engineering history.	In academic community, some materials like BaTiO <sub>3</sub> , or (K, Na)NbO <sub>3</sub> have been investigated, although their materials properties are inferior to PZT in those applications. There is currently no timeline as this is basic research to understand alternatives.	Currently no other material can replace Lead contented PZT ceramic in ultrasonic transducer application without negatively impacting the device performance.
9b	Lead	Lead in Lead-bronze bearing shells and bushes		Needed for table elevation mechanics in XRay, CT, MR and PET.		Although partly covered by 6, it currently also exists separately. Lead in bronze applications of bearing and other moving parts allows long life and high reliability in precision positioning of patients in diagnostic imaging equipment. Position accuracy is critical for successful diagnosis and/or therapy outcome and safety. Minimizes "threading" or particulate generation.
13	Lead	Optical glasses for lenses and filters		Refraction index, optical Quality Color Rendition X-ray reduction to safeguard image sensor. A specific aspect of the use of Lead in glass, for certain applications relates to its shielding properties.	No	Lead in glass is essential for top optical performance, this is especially important for devices that use very small lenses like endoscopes. Medical imaging requires very good color reproduction eg for identification of cancer tissues. *)

Exemption	Substance	Typical Application	Weight put on the EU market	Benefit	Replace	Rationale
13	Cadmium	Optical glasses for lenses and filters		A number of specific physical characteristics.	No	Without such filters sensitive biological samples cannot be protected from UV-radiation, and this is necessary to get a sharp cut-off edge of certain spectral parts. Microscopic applications *)
20	Lead Oxide	Used in glass for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCD)		Technology used in LCD displays. Effective application for bonding LCD substrates for backlighting application.		Needed by any modality employing a flat LCD monitor. Technology may impact the diagnostic capability.
23	Lead	Used in finishes of fine pitch components other than connectors with a pitch of 0.65 mm or less with NiFe lead frames and lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm or less with copper lead frames		For high density parts that are problematic for conversion. This metallization for high pitch parts is required for high reliability.	For high reliable parts, this is the only metallization available for some time to come	This may be the only metallization available for high reliability parts as used by military and aerospace industry. The medical industry needs to take advantage of these high reliability parts which are only available with this lead finish.

Exemption	Substance	Typical Application	Weight put on the EU market	Benefit	Replace	Rationale
25	Lead	Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring as well as in print pastes		Enables the medical industry to continue employing high contrast plasma display panels for high quality displays required for accurate medical diagnosis.		Needed by any modality employing glass plasma displays. Technology may impact the diagnostic capability.
28	Hexavalent chromium	Conductive passivation coating, Eg in Radiotherapy Linear Accelerators	1 kg	Optimal EMC shielding between high-energy power circuits and small control signals. Optimization for the patient by a reliable delivery of treatment	Yes, but not before 2012	Optimal EMC shielding between high-energy power circuits and small control signals. Optimization for the patient by a reliable delivery of treatment Conductivity of the passivation coating (EMC and low signal applications), alternatives are not nearly as good. By 2012 the problem will probably be solved.

\*) See the contribution from the European Optical Stake holders (Spectaris et al)