Joint Medical Industry response to ÖKO-Institut inventory for European Commission "Study on Hazardous Substances in Electrical and Electronic Equipment (EEE), not Regulated by the RoHS"

March 28, 2008

1. Executive Summary

There are a number of risks which must be considered in introducing additional substance restrictions under the RoHS Directive which would then apply to Medical Devices when they are brought within the scope of RoHS. The amount of medical electrical equipment is extremely small (less than 0.25% of the total 12 million tonnes of EEE sold annually in Europe) and the health and safety risks of unexpected failure of Medical Devices, which could cause injury or loss of life, must be considered.

The lack of available information on hazardous substances in Medical Device supply chains means that it is not possible in such a short time frame to provide representative and meaningful data on concentration ranges or possible substitutes / alternatives and advantages / disadvantages of these substances for Medical Device applications. Article 6 of the RoHS Directive requires any adaptation of the list of substances in Article 4 (1) to be based on scientific facts and taking the precautionary principle into account. Proposing the introduction of additional substance restrictions under the RoHS Directive and applying these to Medical Devices without sufficient data represents an unacceptable risk to consumer health and safety (Article 5(1)).

This lack of available information also impacts on gaining regulatory approval from Notified Bodies for Medical Devices. In particular, to avoid conflicts between the RoHS Directive and the Medical Devices Directives, it is essential to ensure that adequate data on alternative substances is available and has been fully evaluated by Notified Bodies before these substances are used in safety critical applications. Furthermore, it is likely that a very large number of exemptions would be required for continued use of these hazardous substances in specific Medical Device applications.

The Medical Device industry also has serious concerns regarding limitations on innovation for new designs of Medical Devices, if inclusion in RoHS does not provide the flexibility to develop new applications of hazardous substances. New Medical Devices are designed to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. In some cases, the physical or chemical properties of hazardous substances could provide

a significant technical advantage that could lead to new products which are beneficial to human healthcare and safety, and where this benefit far outweighs the environmental impacts.

In conclusion, this document reiterates our strongly held position, as stated in its paper to the European Commission of 13 February 2008[1], that any new restrictions on hazardous substances should be carried out under the REACH Regulation. In particular, we note that all substances on the inventory are substances of very high concern (SVHC) under REACH and so will be included in the Candidate List (due for publication in June 2008) and are expected to be included in REACH Annex XIV as substances subject to authorization. Regulation as a substance subject to authorization under REACH is a far more appropriate route as this requires detailed assessment (within an appropriate time frame) of the uses, quantities, control measures for safe use etc so that risks arising from use in Medical Devices can be managed properly. Indeed, if the REACH authorization process determines that certain SVHC represent too high a risk to human health and the environment then it already provides a legal framework for these substances to become restricted under RoHS at that point.

Our position is that REACH provides a much more appropriate mechanism for achieving requirements in Article 6 of the RoHS Directive to take scientific facts and the precautionary principle into account when considering applying additional substance restrictions to Medical Devices.

2. Introduction

Under Article 6 of the RoHS Directive 2002/95/EC, the European Commission is required to

> *"study the need to adapt the list of substances in Article 4 (1),* ***on the basis of scientific facts*** *and* ***taking the precautionary principle into account****, and present proposals to the European Parliament and Council for such adaptations, if appropriate"*

Under Article 5 (1) (b) the Commission is required to establish exemptions from the RoHS Directive for materials and components of electrical and electronic equipment if:

> *"… their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to in Article 4 (1) is* ***technically or scientifically impracticable****, or where the* ***negative*** *environmental,* ***health and/or consumer safety impacts*** *caused by substitution* ***are likely to outweigh the environmental, health and/or consumer safety benefits*** *thereof."*

We also note the following comments in the European Commission summary of comments and information received on the review of the RoHS Directive[2] published in May 2007

[1] COCIR contribution to stakeholder consultation on options for review of Directive 2002/95/EC on RoHS
[2] http://ec.europa.eu/environment/waste/weee/pdf/consultation_comments.pdf

In any case most stakeholders agree that the requirements and developments in the EU chemicals' legislation (REACH) should be carefully considered and ***any overlap with the RoHS directive should be avoided****.*

The European Commission issued tender DG ENV.G.4/ETU/2007/0070r for a *"Study on Hazardous Substances in Electrical and Electronic Equipment (EEE), not Regulated by the RoHS"* and subsequently awarded the contract for this work to Okö-Institut. The tender requires Okö-Institut to identify an inventory of hazardous substances used in EEE as per the following tasks

- *Task 1 (a). Identify which other (non-regulated by RoHS) hazardous substances* ***(meeting the criteria for classification as dangerous in accordance with Directive 67/548/EEC)*** *are used in electrical and electronic equipment.*

- *Task 1 (b). Identify the quantities of these substances, for each of the equipment categories of Annex IA of 2002/96/EC, taking account of REACH tonnage bands<1 t; 1-10 t; 10-100 t as well as the REACH thresholds for substances in articles (substances present in those articles ≥1 tonne per producer or importer of article per year, substance is released under normal or reasonably foreseeable conditions of use, substance is present in those articles above a concentration of 0.1% w/w).*

- *Task 1 (c). Identify whether the use of certain hazardous substances not covered by RoHS* ***is regulated by other pieces of legislation at EU or national level*** *or in third countries and the reasons given for this regulation.*

- *Task 2 (b). For substances identified in Task 1 (a),* ***assess whether the substance would be regarded as a substance of very high concern (SVHC) in the sense of REACH (Regulation 1907/2006).***

- *Task 3 (a). Based on extensive review of existing literature and data bases,* ***examine, to the extent possible,*** *indications about the risks for environment and human health arising from the use of the identified (in task 1a) hazardous substances in EEE and how these risks are managed currently at the various stages of the life cycle of the product* ***(and are likely to be managed in the future, under current legislation)****, in particular end of life management of the equipment in which they are contained.*

- *Task 3 (b). In case additional substances have been identified as candidates for a potential inclusion in RoHS: Possible substitutes available today for the use in EEE and the advantages and disadvantages of these substitutes from a sustainability (environmental, economic, and social) angle; on this basis develop ideas/examine requests for possible exemptions.*

- *Task 4 (a). For each substance considered (under 1a) the contractor should examine,* ***to the extent possible****, options (for example,* ***do nothing,*** *full restriction of the substance,* ***targeted restriction to certain equipment categories,*** *propose specific waste management options for minimising the risks) identified* ***on the basis of available evidence.***

- *Task 4 (b). When elaborating options the contractor should a****ssess whether inclusion in RoHS, compared to potential waste management or other***

policy instruments, is likely in practice to be the most effective way to reduce the risk *taking into account the guidelines on impact assessment*

Accordingly, on 28 February 2008 Okö-Institut issued an inventory of hazardous substances found in EEE and asked for comments on the following points by 28 March (19 working days taking Easter into account):

1. Are there other substances that should be included in the present list of hazardous substances in EEE? ***NB. This has already been addressed in Task 1 (a). Our Industry has not identified any additional substances that should be included in the list.***

2. In which specific components (e.g. in transistors, capacitors, resistors, printed circuit boards, etc.) are the listed hazardous substances contained, including their concentration ranges?

3. Are there risk/exposure assessments available for the listed hazardous substances beyond the EU Risk Assessment Reports?

4. Information on possible substitutes / alternatives for the listed hazardous substances in EEE? Advantages and disadvantages of substitutes?

This document accompanies the detailed comments provided by members on the inventory table and raises a number of critically important issues regarding use of these hazardous substances in Medical Devices. This document:

- Discusses the risks that need to be considered in introducing additional substance restrictions under the RoHS Directive which would then apply to Medical Devices when they are brought within the scope of RoHS.

- Highlights that the lack of available information from Medical Device supply chains means that it is not possible in such a short time frame to provide representative and meaningful data on concentration ranges (Question 2) or possible substitutes / alternatives and advantages / disadvantages of these for Medical Device applications (Question 4).

- Emphasizes that the addition of new substance restrictions to the RoHS Directive impacts on gaining regulatory approval from Notified Bodies for Medical Devices. In particular, to avoid conflicts between the RoHS Directive and the Medical Devices Directives, it is essential to ensure that adequate data on alternative substances is available and has been fully evaluated by Notified Bodies before these substances are used in safety critical applications.

- Highlights Medical Device industry and DG Enterprise concerns that additional substance restrictions under RoHS must not prevent long term investments in future potentially life-saving innovations. In some cases, the physical or chemical properties of certain hazardous substances could provide a significant technical advantage that could lead to new products which are beneficial to human healthcare and safety.

- Reiterates our strongly held position, as stated in its paper to the European Commission of 13 February 2008[3], that any new restrictions on hazardous substances should be carried out under the REACH Regulation. In particular, we note that all substances on the inventory are substances of very high concern (SVHC) under REACH (Task 1 (a) and Task 2 (b)) and so will be included in the Candidate List (due for publication in June 2008) and are expected to be included in REACH Annex XIV as substances subject to authorization.

3. Risks of applying new RoHS substance restrictions to Medical Devices

The Medical Device industry places 30,000 tonnes of electrical and electronic equipment (EEE) on the market in Europe each year. This represents less than 0.25% of the total 12 million tonnes of EEE sold annually in Europe[4].

The main reason why Categories 8 and 9 were originally omitted from the scope of the RoHS Directive was due to concerns over the reliability of certain substitute materials. Although failure of equipment in Categories 1 to 7 and 10 is inconvenient, it does not pose a health and safety risk. In contrast, unexpected early failure of Category 8 Medical Devices can cause injury or loss of life. For example:

- Heart monitors – Failure could result in problems being overlooked with potentially fatal consequences.

- Radiotherapy equipment (cancer treatment) – The applied dose is critical; too little would be ineffective and too much is harmful. Unexpected breakdown is also harmful to patients if treatment is interrupted or delayed.

- Oxygen sensors are used in anaesthetics, intensive care and premature baby incubators to measure oxygen concentrations. Failure or inaccurate measurement could be fatal.

- Defibrillators - failure could result in death of heart attack patients.

- IVD blood analyser – failure could result in incorrect blood tests, including screening for blood borne pathogens such as HIV or Hepatitis B, with resulting health consequences for the individual and the general public.

- IVD bedside diagnostics - test results are used as basis for urgent decisions in emergency cases. Failure or inaccurate diagnosis could be fatal.

<u>Alignment with RoHS legislation in other parts of the world</u>

There is currently no legislative pressure on Medical Devices to comply with RoHS-type restrictions in other parts of the world, either for existing RoHS substances or new substances in the Okö Institut inventory.

[3] COCIR contribution to stakeholder consultation on options for review of Directive 2002/95/EC on RoHS
[4] Comprises 6.5 million tonnes per year of consumer EEE and estimated 5.5 million tonnes per year of business EEE

The Japanese RoHS labelling requirements (J-MOSS) apply to household and IT equipment. There are no plans to extend this to cover Medical Devices or to add new substances to the list.

The California RoHS restrictions (Section 25214.10 of the Health and Safety Code) apply only to video display devices containing a screen greater than 4 inches, measured diagonally, and not to Medical Devices. Two recent attempts to extend the California RoHS restrictions to cover the same scope as the EU RoHS Directive were rejected. There are no plans to go beyond the current scope of the EU RoHS Directive and seek to include Medical Devices, or to add new substances to the list. The China RoHS labelling requirements do apply to Medical Devices, but the Chinese Ministry of Information Industry has indicated that any subsequent material restrictions for Medical Devices are likely to be in line with any RoHS restrictions for Medical Devices introduced in the EU.

The Korea RoHS major requirements were published in April and will come into effect from 1 January 2008. The materials restrictions apply to ten specific product categories – Medical Devices are not included in any of these categories. There are no plans to increase the scope of Korea RoHS to include Medical Devices, or add new substances to the list.

Australia, Taiwan and other parts of the world have not yet introduced RoHS-type restrictions for electrical and electronic equipment.

In summary, the EU is ahead of the rest of the world in its plans for requiring Category 8 Medical Devices to comply with the materials restrictions contained in the RoHS Directive. Furthermore, no other parts of the world are considering adding new substances to their lists of restricted materials.

4. Lack of available information from the supply chain

The lack of available information from Medical Device supply chains means that it is not possible within only 19 working days to provide representative and meaningful data on concentration ranges (Question 2) or possible substitutes / alternatives and advantages / disadvantages of these for Medical Device applications (Question 4).

Hazardous substances in the Okö-Institut inventory were derived from the list of substances which are classified as dangerous in accordance with Directive 67/548/EEC (Task 1 (a)). However, information on the presence of these hazardous substances in electrical and electronic equipment is not communicated up the supply chain to Medical Device manufacturers. This is because there are several tiers in the supply chain between the Medical Device manufacturer and the first user of the chemical substance or preparation to produce components and sub-assemblies.

Directive 2001/58/EC of 27 July 2001 amends for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Directive 67/548/EEC. This requires:

- The person who is responsible for placing a chemical substance or preparation on the market to supply the recipient, who is a professional user of the substance or

preparation, with a safety data sheet, if the substance or preparation is classified as dangerous according to Directive 67/548/EEC or European Parliament and Council Directive 1999/45/EC(7).

- Any person who is responsible for placing a preparation on the market to supply, on request of a professional user, a safety data sheet providing if the preparation is not classified as dangerous according to Articles 5, 6 and 7 of Directive 1999/45/EC, but the preparation contains in an individual concentration of >1 % by weight for non-gaseous preparations a substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits.

The professional user of these safety data sheets is several tiers down the supply chain from the manufacturer of the Medical Device. For example, the company who manufactures the circuit board substrate will receive safety data sheets for the resins that he uses to form the substrate. However, Directive 2001/58/EC notes in Recital (9) that

> *many safety data sheets are of poor quality and do not provide adequate information for the user.*

But any such substance data is lost when the blank circuit board is then sold to a printed circuit board assembler, because there is no requirement for any manufactured product such as this to be accompanied by a safety data sheet. The circuit board assembler then sells the populated circuit board to the Medical Device manufacturer (or other tier in the supply chain), again without a safety data sheet.

In view of this, it is extremely difficult for Medical Device manufacturers to gather representative and meaningful data on the use of hazardous substances in the Okö-Institut inventory in their EEE within only 19 working days. It is certainly not possible to provide representative and meaningful data on

- concentration ranges (Question 2) or

- possible substitutes / alternatives and advantages / disadvantages of these for Medical Device applications (Question 4).

We note that the European Commission has recently run into similar problems in gathering substance information from supply chains in two of its own projects, PRODUCE and SPORT, even though these projects looked at much simpler supply chains compared to EEE and over a much longer time frame.

PRODUCE[5] (Piloting REACH on Downstream Use and Communications in Europe)

The PRODUCE project focussed on testing the workability of gathering information from supply chains on the use of chemicals as ingredients in consumer products, in preparation for REACH. The project lasted six months and closed in December 2005. The project noted that it was a huge challenge to gather the data from the supply chain and that developing the necessary systems and databases will be a considerable time cost to companies.

[5] www.producepartnership.be

SPORT[6] (Strategic Partnership on REACH Testing)

One of the four key objectives of the SPORT project was to test the communication of relevant information along the supply chain. However, the project report of July 2005 notes that communication across the supply chain was very difficult and information flow up and down the supply chain could not be tested as intended.

Scientific facts and precautionary principle

Article 6 of the RoHS Directive requires any adaptation of the list of substances in Article 4 (1) to be based on scientific facts and taking the precautionary principle into account. The above discussion highlights that the necessary data and information to investigate concentration ranges and possible substitutes / alternatives and advantages / disadvantages of these for Medical Device applications is simply not available from the supply chain.

Industry's view is that proposing the introduction of additional substance restrictions under the RoHS Directive and applying these to Medical Devices without the necessary information and data represents an unacceptable risk to consumer health and safety (Article 5(1)). Under the precautionary principle, any such application of new substance restrictions to Medical Devices would need much more extensive data on possible substitutes / alternatives and advantages / disadvantages of these for Medical Devices. In addition, a very large number of exemptions would be required for continued use of the hazardous substances in specific Medical Device applications, resulting in part from the regulatory approvals process for Medical Devices.

5. Regulatory requirements for placing products on the EU market

There are three Medical Device Directives; the Medical Device Directive (93/42/EEC), the Active Implantable Medical Device Directive (90/385/EEC) and the In Vitro Diagnostic Medical Device Directive (98/79/EC). Before Medical Devices can be placed on the EU market they must comply with the 'essential requirements' of the relevant Directive. The essential requirements focus particular attention on ensuring that Medical Devices meet safety and performance levels, and that any risks associated with using the device are acceptable when weighed against the healthcare benefits to the patient.

Depending on the requirements of the relevant Directive and the type of EC Declaration of Conformity chosen by the manufacturer an accredited Notified Body must also examine the design of the products. For manufacturers who maintain a "full quality assurance system" to meet the international standard ISO 13485:2003, the Notified Body performs the examination by assessing the "design dossier". This technical product documentation includes details of all specifications and standards that the manufacturer has applied to design the product and the verification and validation results. The manufacturer can only apply the CE mark to the product, so that it can be sold in the EU, if the Notified Body affirms that the product conforms to the requirements of the relevant Directive.

Conformity assessment for Medical Devices

[6] www.sport-project.eu

Where an existing product is changed in order to comply with RoHS, the manufacturer must inform the Notified Body that carried out the conformity assessment for the product. Manufacturers must provide evidence that reliability has not been negatively affected by use of alternative substances. Where any doubts remain, this could result in failure to gain approval by the Notified Body. This is particularly important for the most safety critical products such as implanted devices.

Article 2 (2) of the RoHS Directive notes that

> *"This Directive shall apply without prejudice to Community legislation on safety and health requirements and specific Community waste management legislation".*

To avoid conflicts between the RoHS Directive and the Medical Devices Directives, it is essential to ensure that adequate data on alternative substances is available and has been fully evaluated by Notified Bodies before these substances are used in safety critical applications. Accordingly, the European Commission must take advice from Notified Bodies on whether data on alternative substances is sufficient to ensure that use of these alternative substances will enable Medical Devices to meet the essential safety and performance requirements in the relevant Medical Device Directive.

In many cases adequate data may not be available yet and the Notified Bodies are not able to approve the use of alternative substances in safety critical applications. Accordingly, it is likely that a very large number of exemptions would be required to allow continued use of certain hazardous substances in the Okö Institut inventory in specific Medical Device applications. These exemptions would need to remain in force until the Notified Bodies' opinion is that the alternative substances can be used in safety critical applications.

The length of time to gain approval from a Notified Body depends on the complexity of the change and if adequate test data is available. The approval process can take a few weeks but six month is not uncommon for more complex products. Many Notified Bodies are already very busy. The increase in workload to re-approve all existing products against new RoHS substance restrictions (not to mention the existing RoHS substances) would cause further delays so that, in some cases, approval could take up to one year. In the mean time, the compliant version can not be sold in the EU.

<u>Availability of trained engineers</u>

In addition to the time required to test and validate any required engineering design modifications the manufacturer has to compile the reliability testing data into a revised technical file, when submitting a RoHS compliant version for approval. For the most complex products, testing and validation can take 18 months or more. The number of trained engineers available to carry out this work is limited. For a manufacturer with a very large range of products, the time required to test and to validate all of the design modifications and re-submit the technical files can be very long.

6. Limitations on innovation

Limitations on innovation for new designs of Medical Devices are a serious concern both to the Medical Device industry and also for DG Enterprise, which has responsibility for Medical Devices within the European Commission.

Innovations are continually introduced into all products in all of the WEEE categories. Many of the substances on the Okö Institut inventory are unlikely to be used in new innovations for new products in Categories 1 to 7 and 10. However, this will not have a negative effect on human health or safety – the only impact would be the potential loss of some new features on these products.

New innovations for new Medical Devices are designed to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. In some cases, the physical or chemical properties of hazardous substances could provide a significant technical advantage that could lead to new products which are beneficial to human healthcare and safety.

Clear legal basis so that RoHS Directive does not prevent innovation

Innovative new designs require considerable investment and time to bring them to market. The Medical Device industry is concerned that a clear legal basis is needed so that the RoHS Directive does not prevent these long term investments in future potentially life-saving innovations.

Unfortunately there are few options available within the limitations of the RoHS Directive to allow unrestricted innovation.

7. Conclusion: new substances restrictions should be under REACH

We note that all of the substances on the Okö-Institut inventory are substances of very high concern (SVHC) under REACH (see Task 1 (a) and Task 2 (b)) and are identified as high priority based on CMR, PBT / vPvB or endocrine disruptor characteristics. On this basis, they will be included in the Candidate List (due for publication in June 2008) and are expected to be included in REACH Annex XIV as substances subject to authorization. Therefore, these substances are already covered by REACH and will be regulated under REACH through the authorization process.

Task 1 (c) requires identification of whether the use of hazardous substances in the Okö-Institut inventory is regulated by other EU legislation, and Task 3 (a) requires identification of how risks to environment and human health from the use of hazardous substances are likely to be managed in the future, under current legislation.

Our position is that these substances are already covered by REACH and will be regulated under REACH authorization process, and so should not be separately considered for restriction under RoHS. Our views are in line with the following comments in the European Commission summary of comments and information received on the review of the RoHS Directive[7] published in May 2007

[7] http://ec.europa.eu/environment/waste/weee/pdf/consultation_comments.pdf

In any case most stakeholders agree that the requirements and developments in the EU chemicals' legislation (REACH) should be carefully considered and ***any overlap with the RoHS directive should be avoided****.*

As stated in our paper to the European Commission of 13 February 2008[8], the medical device industry strongly believes that any new restrictions on hazardous substances should be carried out under the REACH Regulation. The REACH authorization process requires detailed assessment (within an appropriate time frame) of the uses, quantities, control measures for safe use etc so that risks arising from use in Medical Devices can be managed properly. Indeed, if the REACH authorization process determines that certain SVHC represent too high a high risk to human health and the environment then REACH already provides a legal framework for these substances to then become restricted under RoHS at that point.

We strongly believes that regulation as a substance subject to authorization under REACH is a far more appropriate route, particularly for Medical Devices. In particular, this provides a much more appropriate mechanism for achieving the requirements in RoHS Article 6 to take scientific facts and the precautionary principle into account when considering applying additional substance restrictions to Medical Devices.

[8] COCIR contribution to stakeholder consultation on options for review of Directive 2002/95/EC on RoHS