



RoHS Recast

COCIR'sⁱ additional point on Medical Device exemptions

Brussels, 1 June 2010

In view of the **upcoming European Parliament Environment committee** vote on the proposal for a recast of Directive 2002/95/EC on the Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), **COCIR fully supports** the key issues summarized in the joint industry statement issued on 28 May¹.

Together with other industry organizations, COCIR kindly request your support to:

1. clarifying RoHS scope exclusions,
2. introducing formats, timelines and grace periods for RoHS exemptions case by case,
3. establishing a structured stakeholder consultation mechanism,
4. assessing the added value of the RoHS Directive during the REACH review process and in the meantime align RoHS with REACH to the maximum extent,
5. aligning RoHS with the New Legislative Framework, and in particular to make use of European Standardisation Committees to harmonise relevant standards.

Because of COCIR's highly innovative and complex healthcare technology with comparably long life cycle expectation and the many potential failure mechanisms (e.g. of substitutes) affecting long-term reliability, **COCIR considers it is indispensable to adopt the recommendation summarised in the 2009 ERA Report.**

COCIR fully supports tabled **Amendments 319 to 335**, updating the wording of existing exemptions for category 8 as well as essential additional exemptions for medical devices.

COCIR stresses the **importance** of exemptions as suggested by ERA² in order to:

- **continue to provide safe and effective medical** devices to the EU market contributing to a better healthcare system improving citizens' quality of life,
- **ensure sufficient time** to find alternative components (research), re-design products, conduct validation and reliability testing and obtain market approval to comply with Medical Devices Directives.

If such exemptions are not validated we run the **risk** to compromise the availability of medical devices and the future development of new technologies. It was proven that none of the apparent substitutes were suitable as of today.

¹ Joint Industry Statement of 28 May 2010: <http://www.cocir.org/content.php?level1=14&level2=&mode=24&id=67>

² The **ERA Report of September 2006** (ERA Report 2006-0383, Table 44 & 71) concludes to extend the original RoHS scope to category 8 (and 9) on the basis of exemptions for specific applications granted in Annex V and Annex VI. The updated **ERA Report of September 2009** (ERA Report 2009-0394, p. 56-58) updates Annex VI according to the latest scientific findings (the report is available at http://www.cocir.org/uploads/documents/8-998-2.1_era_report_on_rohs_exemptions_for_medical_devices_released_version_21_sept_2009.pdf).

ⁱ **COCIR Company Members:** Agfa-Healthcare, Alcon, Alert, Aloka, Bosch, Canon Europe, GE Healthcare, Hitachi Medical Systems Europe, Hologic, IBA Ion Beam Applications, IBM, Intel, Isoft, Carestream Health, Fujifilm, Elekta, Konica, Medison, Microsoft, Philips Healthcare, Siemens Healthcare, Shimadzu, Toshiba Medical Systems Europe

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