



Healthcare Industry recommendations on RoHS (June 2009)

Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) - COM(2008)809 of 03 December 2008 -

The Healthcare Industry fully supports the underlying aims of the RoHS Directive – to contribute to the protection of human health and the sound recovery and disposal of waste electrical and electronic equipment. The Healthcare Industry also supports the Commission proposal to extend the scope of the proposal to medical devices (category 8 in Annexes I and II).

To further improve the proposal the Healthcare Industry would like to highlight seven important points which would need to be addressed in order to maintain the current high level of quality and safety of medical devices and to further allow the innovative capacity of the sector necessary for continuing improvements of patient care.

(1) Management of exemptions (Article 5, paragraph 2)

The Commission proposal for the management of exemptions will give rise to legal uncertainties. The principle that exemptions are to be reviewed periodically is already well established, for example in REACH. However, the RoHS proposal could be interpreted in a way that exemptions could expire after four years without having had any review. This kind of process could lead to a severe disruption in the availability of medical devices for patients. Furthermore, it would discourage research and development efforts in potentially health enhancing, life prolonging and even life saving innovations. To avoid these adverse effects, industry would need legal certainty that exemptions could be extended in cases of a duly justified technical situation.

- ***The management of exemptions should be based on a periodically and case-by-case review process. It should avoid an automatic expiration after four years and allow reasonable transition times for phasing in alternative substances if they are technically and economically feasible and without any risk to the function of the product and therefore to the health of the patient. An example could be the provisions laid down in the REACH legislation (Article 60, paragraph 8).***

(2) Declaration of conformity – Compulsory format (Article 13, Annex VII)

The RoHS proposal includes a compulsory format for declarations of conformity. All medical devices covered by RoHS are already subject to a declaration of conformity under their respective Directive. The standard which defines how the declaration should look like is the EN ISO 17050¹ standard. The RoHS proposal should therefore encourage the use of this existing standard instead of introducing a new format and thus require changing the format of thousands of declarations of conformity, which would cause a heavy administrative burden without any further benefit to the safety of products.

- ***Annex VII should be available as an optional format. This would still allow the use of the existing EN ISO 17050 standard and avoid bureaucratic burden with no safety benefit.***

¹ EN ISO 17050: Conformity Assessment – Supplier's declaration of conformity.



(3) Conformity Assessment Route (Article 7, paragraph 2)

The current proposal imposes a conformity assessment route referred to as “internal production control procedure” as set out in Annex A of Decision 768/2008/EC. For those devices which are already subject to a more stringent conformity assessment route under specific sector legislation (such as the medical devices Directives) this would impose a significant additional bureaucratic burden without any additional benefit for conformity or safety of the device.

- ***Existing, more stringent conformity assessment routes should be accepted, where they are already required by specific sector legislation.***

(4) Extension of Annex IV to include new substances (Article 4, paragraph 7 and Annexes III and IV)

If new substances are considered to be added to the list of restricted substances (Annex IV), the impact on medical devices must be assessed separately avoiding any unjustified risk to the availability of medical devices to patients. This would reflect the particularly long development cycles and the need for additional exemptions to ensure reliability and safety for medical devices.

- ***All new substances which are considered to be included into the RoHS Directive should be addressed under REACH, where the procedure for authorisation is well established. Double regulation needs to be avoided.***

(5) Labelling requirements, addresses (Article 7, paragraph 7)

The contact addresses given under the medical devices directives are critical for medical device safety and medical device vigilance and should take precedence over other contact information so as not to be confusable. It is important that information critical to patient safety and medical device vigilance is not misdirected. The RoHS proposal would need clarification in this respect.

- ***Where the manufacturer and authorized representative are already identified on the product under specific sector legislation, these should be the only contacts identified on the product label.***

There are some provisions already included in the RoHS proposal which are seen as key to the successful extension of the scope to category 8 devices by the Healthcare Industry:

(6) Transition times (Article 4)

The transition times laid out in Article 4 (2014 for medical devices covered under 93/42/EEC and 2016 for in vitro diagnostic medical devices covered under 98/79/EC) are indispensable to allow for a smooth implementation of RoHS for medical devices with minimal disruptions in supply to the healthcare system.

(7) Specific exemptions for Category 8 (Annex VI)

The Healthcare Industry fully supports the current list of exemptions for category 8 (medical devices). The technical validity of these exemptions has been assessed in detail by the Cobham (formerly ERA) report². Further exemptions are currently being independently scientifically evaluated and should be included in the RoHS Directive if duly justified.

² Review of directive 2002/95/EC (RoHS) categories 8 and 9; final ERA Report number 2006-0383.