ORGALIME

Position Paper

Brussels, 5 November 2010

PROPOSALS FOR FURTHER PROCEEDINGS IN TRIALOGUE NEGOTIATIONS

Considering that the European Parliament and Council are negotiating on a first reading agreement on the Commission proposal, Orgalime would like to contribute to the debate. In our Position Paper: *Main priorities and proposals for further proceedings on RoHS recast* of 19 July 2010, we expressed our fundamental requests when shaping the RoHS recast, which are:

- A harmonised and non ambiguous scope with a comprehensive set of exclusions;
- An alignment of RoHS with REACH & NLF;
- Clear criteria and procedure for granting RoHS exemptions.

In addition, we would like to request your active support for addressing the following additional concerns:

1. **The need for a substance evaluation methodology and exemptions consistent with the REACH Regulation**

There should be clear criteria and procedures for identifying and evaluating substances before restricting substances in electrical and electronic equipment. The substance evaluation methodology under RoHS should, in our view, be consistent with REACH and particularly assesses waste phase impacts of a substance from a life cycle perspective.

To review and amend Annex IV, the Commission should ensure that all relevant information required in Article 6a.2, which need to be gathered in the Dossier to propose additional substances restrictions, are unambiguously taken into consideration in the ultimate justification whether to restrict new substances. Moreover, the evaluation methodology should not follow a "group of similar substances" approach. Substances should be evaluated on an individual basis for the following reasons:

- Substances within a group can have significantly different properties including (eco-) toxicological profiles. Thus the toxicological properties of one substance with classification as hazardous might not render an entire group of substances collectively hazardous.
- Scientific evidence and impact assessment should exist for each individual substance prior to discussion about substance restrictions.
- The reference to "similar substances" is an indefinite quantity which cannot be precisely identified. Considering that materials declarations are based on EC or CAS numbers to reference discrete substances and that conformity assessment and RoHS enforcement in general may be based on analytical tests which are substance specific, then a group of substances approach might render these common practices impracticable.

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We therefore propose that Article 6a.1 (third paragraph) and Article 6a. 2 read as follows:
"…… To review and amend Annex IV, the Commission shall ***consider all information required in Article 6a.2 and*** *take special account of whether the substance, whatever its particle size~~, or~~ […] ~~a group of similar substances~~: ….."*

"…... The proposals to review and amend the list of substances~~, or a group of similar substances,~~ in Annex IV shall contain at least the following information:
- *Precise and clear wording of the proposal,*
- *Referenced and scientific evidence for the restriction,*
- *Information on the use of the substance ~~or the group of similar substances~~ in EEE,*
- *Information on detrimental effects and exposure, in particular during waste EEE management operations,*
- *Information on possible substitutes and other alternatives, their availability and reliability,*
- *Justification for considering an EU-wide restriction as the most appropriate measure,*
- *Socio-economic assessment."*

In addition, to reduce unnecessary administrative burden and ensure consistency between EU legislation, the relationship between REACH authorisations, REACH exemptions from authorisation and RoHS exemptions need to be further clarified.

2. The need for necessary exemptions of applications for Medical Devices and applications in a heavy duty industrial surrounding

The RoHS Recast directive may have significant impact on e.g. Europe's Healthcare System and citizens' access to state of the art Healthcare, in case exemptions for specific already well understood applications are not validated within the recast before Medical Devices come into the scope. New Medical Devices intended to give better and earlier diagnosis, more effective and successful treatment and completely new treatments, which use such exemptions, would no longer be marketed in Europe. For example, the two following innovative technologies would no longer be available in Europe:

- High technology components manufactured for other sectors (currently not within scope of ROHS), and applied by the Healthcare industry such as robotic arms used to position patient tables for particle therapy of cancer;
- Magnets and other components used in accelerators to deliver proton therapy, another advanced form of cancer treatment.

Advancement of medical technology in the field of prevention, diagnostic and therapy are essential to meet the challenges of an aging society. Today no alternative are available to meet the current high reliability and quality requirements. Against the background of complex healthcare technology with comparably long fundamental research cycles of 5-10 years and typical product design cycles of 3-5 years, the question of needed exemptions cannot be delayed.

Orgalime therefore supports the rejection of amendment 51.3.e that challenges the applicability of the existing RoHS exemptions listed in annex V of the Commission proposal for categories 8 and 9. In addition, Orgalime would suggest re-introducing EP Amendments 91 to 99, which include, in Annex VI, exemptions as originally proposed by the Commission. These are based on a first report issued by Cobham Technical Services[1] (ERA Technology) in 2006 and overview of additional exemptions needed highlighted in the second report of Cobham Technical Services[2] released in 2009.

[1] *See http://ec.europa.eu/environment/waste/pdf/era_study_final_report.pdf*
[2] *See http://www.cocir.org/extranet/uploads/documents/-1014-era_report_on_rohs_exemptions_for_medical_devices_sept_2009.pdf*

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Orgalime would like to remind regulators of the ongoing emergency postponement and now review of the directive on exposure of workers to Electromagnetic Fields and Waves that had to be introduced following the adopting of legislation which effectively made it impossible to use IRM scanners as well as other professional equipment.

3. The need for necessary exemptions allowing free circulation of CE marked refurbished of medical equipment and products used in a professional surrounding (B2B)

For example, refurbished Medical Devices are an integral part of today's Healthcare infrastructure. The Healthcare industry has developed a well-advanced concept of refurbishment to serve the EU and US markets, which request 50% percent of the globally available refurbished devices, with "safe and effective equipment as when new". Refurbished equipment is based on available products on the global market that are taken back and properly refurbished by the original manufacturer according to a globally accepted Good Refurbishment Practice standard.

Orgalime therefore supports exemptions of cables or spare parts for the repair or to the reuse, and for recalibration or updating of functionalities or upgrading of capacity. However, Article 4.4 does not sufficiently address the case of free circulation of refurbished medical devices that follows the concept of re-use. The absence of clear exemptions allowing the free circulation of CE marked refurbished equipment will mean that the European market for refurbished medical devices will collapse. As a consequence, European Healthcare systems would have to cope with raising costs and it would force the production of new equipment which uses up to 70% more resources compared to re-using already available devices in a different hospital.

With 70% of refurbished medical equipment needed for Europe coming from outside the Community, the concept of re-use of electromedical equipment and free circulation of equipment which bears the CE marking independent from the first placing on the global market is indispensable. To properly address of free circulation of refurbished medical devices, Article 4.4 should in our view read as follows:
" Paragraph 1 shall not apply to cables or spare parts for the repair, […] the reuse ***of EEE and its parts****, the updating of functionalities or upgrading of capacity of the following:*
(a) EEE placed on the market before 1 July 2006
(b) Medical devices ***and their parts covered by a CE mark and are*** *placed on the* ***Community*** *market* ***or outside*** *before […] [three years after the date of entry into force].*
(c) In vitro diagnostic medical devices ***and their parts covered by a CE mark and are*** *placed on the* ***Community*** *market* ***or outside*** *before […] [five years after the date of entry into force] ....."*

4. The need for clear definitions of "Non-road mobile machinery" and "dependant"

Orgalime believe that proper definitions are required to secure fair competition and legal certainty. However, for example, the latest change in the definition of "non road mobile machinery" will further narrow the exclusion of this type of machinery from the scope of RoHS. The addition of the words "*with an onboard power source*" intends to include machinery that is simply plugged-in with the power cord into an electrical socket in the scope of the recast RoHS Directive.

Orgalime does not support this modification. It would lead to the paradoxical situation that mobile machinery for professional users which is identical in construction except the fact that one has a battery and the other is a plug-in machine will be treated differently - one has to be RoHS compliant but the other not. Since the definition of non road mobile machinery as it was before is clear and sufficient, Orgalime would suggest to stick with the previous definition.

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Moreover, where existing, such definitions should be based upon definitions provided in existing legislation applying on electrical and electronic equipment. For example, the definitions of the term "*dependent*" should, in our view, be in line with the Commission's F.A.Q.s guidance document of 2006.

Orgalime therefore suggest amending the definition of the term "dependent" (Article 3.aa) as follows:
"*dependent" means that the ~~electrical and electronic~~ equipment needs ~~electric currents or electromagnetic fields~~* ***electricity as its primary energy*** *to fulfil its* ***basic*** *~~at least one intended~~ function*"

5. The need for an alignment with the New Legislative Framework

The RoHS recast should, in our view, be an opportunity to also strive for better consistency with the New Legislative Framework (NLF). However, a number of modifications introduced in the latest compromise proposal would undermine the NLF, such as manufacturer and importer obligations to a keep register of non complying EEE, set out in Article 7 and 9, which go beyond the NLF requirements will increase administrative burdens.

Therefore, Orgalime proposes to stick with the NLF approach regarding manufacturer and importer obligations, the concept of CE marking, and the presumption of conformity, so as to avoid unnecessary administrative burden and to ensure more consistent EU legislation.

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