ORGALIME

Position Paper

Brussels, 16 February 2009

MAIN COMMENTS ON COMMISSION RECAST PROPOSAL FOR DIRECTIVE 2002/95/EC (RoHS)

COM (2008)809/4

Orgalime kindly requests the support of European regulators for the following initial comments on the Commission's proposal of 3.12.2008 for amending Directive 2002/95/EC on Restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS):

- The RoHS recast proposal claims to simplify existing legislation and to avoid unnecessary bureaucracy and administrative costs in line with Better Regulation principles of the EU. However, the RoHS recast proposal in our view fails to realise this objective, in particular since it overlaps with other legislation and thereby creates legal uncertainty. Therefore, Orgalime's fundamental request to regulators is to ensure **full legal consistency** between the RoHS Directive and other legislative initiatives, in particular with the REACH Regulation and New Legislative Framework (NLF) that have been finalised after the adoption of the initial RoHS Directive.

- Regulation 1907/2006 on the Registration, Evaluation, Authorisation of Chemicals (REACH), which entered into force on 1 June 2007, provides a fully harmonised framework for chemicals management across the EU and includes substances in electrical and electronic industries in its scope. To avoid disruption in our highly complex global supply chains, legal uncertainty, unnecessary duplication of administrative burden and costs as well as knock on effects on our client industries resulting from potential conflicting requirements under different EU laws, it is vital that **any revision of the RoHS directive fully implements <u>all</u> REACH criteria and procedural elements for establishing any further substance restrictions in EEE.** This has to particularly include the full application of articles 69-73 REACH for the evaluation of new substances and all the responsibilities that REACH assigns to the European Chemicals Agency and various committees involved in the preparatory process for substance restrictions.

- We welcome the proposal to streamline RoHS with the New Legislative Framework and especially support a strong role for **standardisation** for the implementation of the directive. International standardisation bodies have agreed on standards, which are also appropriate to underpin RoHS compliance for the future. Provided that standardisation is finally mandated to develop details of RoHS compliance, industry supports the inclusion of the levels of maximum concentration values and a definition of homogeneous material in the legal text of the RoHS directive. However, the proposed definition of "homogeneous material" unfortunately still risks causing confusion and legal uncertainty for companies and should therefore be revisited. The final definition of homogeneous material shall serve as the common base for further specification in standardisation, especially on sample preparation.

Orgalime, the European Engineering Industries Association, speaks for 35 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs over 11 million people in the EU and in 2007 accounted for some €1,813 billion of annual output. The industry not only represents more than one quarter of the output of manufactured products but also a third of the manufactured exports of the European Union.

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- We are concerned with the proposed "one size fits all"- **maximum validity period of 4 years for all RoHS exemptions**, which is further reduced to 2 ½ years in practice via the proposed deadline of filing requests for renewals of any exemption already 18 months before the end of the validity period at the latest. Considering innovation and investment cycles for EEE, the proposed timescales are unrealistic, creating a high level of legal uncertainty in the market place that is neither workable, nor in line with the REACH Regulation, nor enforceable.
  To clear supply chains, to carry out necessary testing and to implement reliable alternative solutions without compromising the functionality, technical and safety reliability of EEE, industry needs **realistic time frames for the review and validity of the individual exemptions on a case by case basis**. Such a way forward is also recommended by the Commission's own preparatory RoHS study carried out by the Ökoinstitut. We also strongly reject the implementation of a fixed validity date for those exemptions, where no technical alternatives exist at the time of stakeholder consultation. This would impose legal uncertainty and high economic risk to those companies having no alternative, but fully depending on a, to date, unforeseeable decision making process without any time limits for the Commission to take a final decision.

- Orgalime does not generally reject the proposed **inclusion of medical devices and monitoring and control equipment** in the evaluation process for possible substance restrictions (categories 8 and 9). However, establishing restrictions in such equipment should equally apply all criteria and procedural elements of REACH and exemptions need to be granted in a foreseeable process that allows realistic time scales and the possibilities for renewals of any exemption as outlined in the previous point. It is all the more important to balance the potential risks that such equipment could cause to the environment with the indisputable health benefits that medical devices provide to patients and the indisputable safety benefits that monitoring and control equipment provides to industrial clients and workers.

We call upon on the European Parliament and the Council to take these comments into account in the further proceedings and look forward to providing further substantiated information and input to the legislator.

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