ORGALIME

Position Paper

Brussels, 19 July 2010

MAIN PRIORITIES AND PROPOSALS FOR FURTHER PROCEEDINGS ON RoHS RECAST

EXECUTIVE SUMMARY

On 10 June 2010, the Environment Committee of the European Parliament has adopted the Report of Rapporteur Evans on the Commission proposal for a recast Directive 2002/95/EC on the Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS). The Environment Council has presented its progress report on the issue on 11 June 2010. We understand that the institutions have agreed to enter into discussions on a possible first reading agreement.

Considering that several substantial proposals for modifications to the initial Commission proposal are suggested by the EP or the Council, Orgalime is highly concerned with the intention to finalise discussions in first reading and invites the institutions to take the necessary time to arrive at quality legislation, which is workable and enforceable in practice, and to particularly consider the comments and proposals included in this document in its further proceedings.

MAIN PRINCIPLES IN THE LIGHT OF BETTER / SMART REGULATION

Our industries ask regulators to secure the following main principles in the further proceedings on the RoHS recast:

- Carrying out a representative impact assessment at EU level for any substantial change to the existing directive, such as for the far-reaching proposals for an open scope or new substance restrictions on nanosilver and nanotubes
- Sticking with the remits of a recast to fine-tune areas where the implementation process has shown shortcomings instead of upsetting the complete structure of the Directive, such as through cutting off RoHS from the broader EU's chemicals framework REACH or introducing further inconsistencies with the New Legislative Framework
- Reducing unnecessary administrative burden and related costs, which would result from parallel requirements on same products and substances under RoHS and other EU legislation, and REACH in particular
- Allowing for assessing the added value of the RoHS Directive during the REACH review process and in the meantime aligning RoHS with REACH to the maximum extent
- Aligning RoHS with the New Legislative Framework (NLF)

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MAIN INDUSTRY REQUESTS WHEN SHAPING RoHS

Our industries ask regulators to support the following main proposals:

- Opting for a truly harmonised scope in the RoHS Directive itself that improves the current situation in terms of legal certainty and predictability for producers of electric and electronic equipment – an open scope does not contribute to clarifying remaining interpretation issues under the existing directive but introduces more questions than answers
- In any case, introducing a concise but comprehensive set of scope exclusions
- Applying a substance evaluation methodology under RoHS that is fully consistent with REACH and particularly assesses waste phase impacts of a substance from a life cycle perspective
- Introducing clear criteria for filling the new annex III list of substances for evaluation and rejecting duplication of assessments by listing same substances under annex III and the REACH candidate list – As long as there is no appropriate methodology for evaluating substances prior to setting new restrictions, preferably annex III should be removed or at least, the Commission proposal for annex III should not be extended
- Rejecting any immediate new substance restrictions in annex IV, such as proposed for nanosilver and nanotubes
- Evaluating and, where necessary, regulating nanomaterials under REACH instead of RoHS
- Accepting the socio economic criterion and the criteria of availability and reliability of substitutes for granting RoHS exemptions
- Introducing formats for RoHS exemptions
- Introducing validity periods and grace periods for RoHS exemptions case by case
- Supporting that for existing RoHS exemptions and finally approved future RoHS exemptions, no REACH authorisations should have to be sought
- Clarifying how far authorisations granted under REACH would account for possible exemptions under RoHS
- Making use of European Standardisation Committees to harmonise relevant standards for facilitating RoHS compliance
- Establishing a structured stakeholder consultation mechanism during the implementation of the recast directive

We specify our concerns and concrete proposals in more detail hereafter:

1. SCOPE

Concerns:

- The consequences of the proposal for an open scope remain unknown today. Carrying out an impact assessment before taking a decision is not only a prerequisite in terms of Better Regulation, it will also help to close knowledge gaps and to avoid undesired negative consequences, including in particular on SMEs, while identifying areas where real environmental gains can be achieved.
- Scope exclusions cannot compensate for the proposal for an open scope. Where it is however already indicated today that negative consequences can be expected, scope exclusions must in our view be granted.

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- Scope exclusions require proper definitions to secure fair competition and legal certainty. Where existing, they shall be based upon definitions provided in existing legislation applying on electrical and electronic equipment.
- The EP ENVI Committee proposes that the Commission shall submit a report and legislative proposals for further scope exclusions where appropriate. This cannot compensate for the proposal for an open scope either, since it will not give sufficient predictability to producers whether or not their product may fall under the scope.
- Regarding categories 8 and 9, the implementation dates of 1.1.2014, 1.1.2016 and 1.1.2017, as included in article 4.3 of the Commission proposal, need to be maintained.
- Regarding cables, we would like to stress that cables that form part of the EEE itself are already covered by the directive. For any further extension of the scope, including industrial/professional cables, no impact assessment has been carried out. We therefore object to their inclusion in the scope. In addition, such cables represent products handled by professionals and as such will not end up in the municipal waste stream or in dustbins.
- The RoHS Directive regulates electrical and electronic equipment, which we support. Including consumables and accessories in its scope, however, would mean that products that are of non-electric/electrical nature, (e.g.: printer paper, vacuum cleaner bags, water filters in coffee machines) would fall under its scope, too. This, we do not support.

Proposals:

- **Reject EP amendments 20, 21, 26, 35, 85, 86 of the Report of Rapporteur Evans**
- **Art. 2.3 should include at least the following scope exclusions:**
  - military equipment
  - equipment which is part of another type of equipment outside the scope
  - equipment not intended to be placed on the market as a single functional or commercial unit
  - fixed installations
  - large scale stationary industrial tools
  - mobile machinery
  - any means of transport
  - active implanted medical devices
  - non electrical and electronic consumables and accessories
  - equipment for research and development
  - renewable energy generation technology
  - spare parts for the repair and upgrade of functions of equipment placed on the market before the entry into force of substance restrictions.
- **Support EP amendment 23 of the Report of Rapporteur Evans, but:**
  - **replace** the notion "*except monitoring and control equipment*" by "*except monitoring and control instruments*" in litera (bb), and
  - **remove** the last paragraph, which reads: "*No later than, the Commission shall submit a report…., if appropriate.*"
- **Support EP amendments 42 and 43 of the Report of Rapporteur Evans, but:**
  - **delete the sentence** "*It shall not include …part of that installation.*"
- **Support EP amendment 44 in principle, but:**
  - **replace the reference to Exhaust Emissions Directive by a reference to Machinery Directive**
- **Support EP amendments 12 and 41 of the Report of Rapporteur Evans**
- **In line with the Commission's F.A.Q.s guidance document, the term "dependent" shall be defined as follows in article 2:**
  "*dependent means that the equipment needs electricity as its primary energy to fulfil its basic function*"

2. METHODOLOGY FOR EVALUATION OF SUBSTANCES PRIOR TO SETTING RESTRICTIONS

Concerns:

- Orgalime supports that there should be clear criteria and procedures for identifying and evaluating substances before restricting substances in electrical and electronic equipment. This improves transparency and increases the quality of legislation.
- However, the EP ENVI Committee as well as the Council propose to evaluate all substances listed on the annex III-list on the basis of a flawed substance evaluation methodology, which would be almost entirely cut off from REACH and no longer have to be in accordance with articles 69-72 REACH. Since all substances listed on the REACH candidate list would be included in the Committee's extended RoHS priority list of annex III, our industries will face duplicated evaluation procedures for the same substances in the same products.
- This proposed independent RoHS methodology for substance evaluation isolates the assessment of the end of life impacts of a substance from its impacts during other life cycle stages, such as the use phase. This of course will inevitably lead to contradictions with other major EU policies, such as on Energy and Climate Change and most likely to undesirable environmental impacts. The REACH Regulation and several ECHA guidance documents clearly specify that REACH assessments cover the waste phase and especially the end of life aspects of electrical and electronic equipment, such as milling or incineration.[1]
- Any substance evaluation methodology should follow a risk based approach, which is also not the case for the independent RoHS methodology proposed by the EP ENVI Committee or the Council.
- The EP Environment Committee introduces an annex III - priority list of 36 (groups of) substances for evaluation for future restrictions under RoHS. Apart from the fact that there has been no impact assessment for all the additions made to annex III, there is no clarity on the criteria or procedure for selecting substances to be added to annex III, which in our view would have to be a prerequisite.
- The extension of the list of annex III is increasingly of concern, since it is combined with a RoHS methodology for evaluating these substances that is independent from REACH. We are concerned with the overlap of the proposed annex III with the REACH candidate list (which is the pre-step of the annex XIV list of REACH on substances to be authorised), which will result in a duplication of evaluation processes and unnecessary administrative burden for companies, in particular SMEs, as well as authorities.

Proposals:

- **Support EP amendment 18 of the Report of Rapporteur Evans**
- **Reject EP amendment 54 of the Report of Rapporteur Evans**
- **Reject Council proposal for article 6a of 21 May 2010**

[1] See article 3.(37) REACH, annex I paragraph 5.2.2 REACH, annex I paragraph 5.1.1 REACH and annex II REACH; ECHA guidance on information requirements and chemical safety assessments, chapter "R.18: Estimation of exposure from waste life stage", which includes a section "R.18.5.2.3 Emissions from milling vehicles and electrical/electronic good" and "other waste operations" such as landfill, incineration and dismantling processes or the release from other waste treatment operations" (see page 16f); ECHA Guidance on information requirements and chemical safety assessments, pages 21,30, 38, 41, 42; ECHA Guidance for the preparation of Annex XV dossiers for restrictions, page 57, which reads that the information on hazard and exposure and risk characterisation needs to include, amongst other things, "in which life cycle stage(s) the exposure resulting in risk occurs"; ECHA Guidance on Substance Evaluation, p.51 and appendix 6.

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- **Article 4.7 or article 6a RoHS should read as follows:**

"*Article …*

When there is an unacceptable risk to human health or the environment, arising from the use of substances, and in particular the substances listed in Annex III, which needs to be addressed on a Community-wide basis, the list of prohibited substances in Annex IV shall be reviewed using the methodology established in Articles 69 to 72 of Regulation (EC) No 1907/2006.

In particular, the methodology of evaluating substances for the purpose of this Directive shall be based on sound science, representative and reliable data and any relevant chemical safety report or risk assessment submitted under Regulation (EC) No 1907/2006. That methodology shall, inter alia, include an impact assessment of alternatives, and take into account:

(a) socio-economic impacts

(b) the availability and reliability of alternatives

(c) the positive and negative impacts on human health and safety of substances and their potential alternatives related to

- *all relevant life cycle phases, including end-of-life scenarios of reuse, recycling and treatment of WEEE,*
- *uncontrolled or diffuse dispersion to the environment,*
- *exposure of these substances to workers and the environment.*

To contribute to a high level of protection of human health and the environment, the methodology shall be consistent with other legislation related to chemicals, in particular Regulation (EC) 1907/2006 (REACH) and the knowledge obtained from the application of such legislation."

- **As long as there is no appropriate methodology for evaluating substances prior to setting new restrictions, annex III should preferably be removed or at least, the Commission proposal for annex III should not be extended. Consequently, EP amendment 87 of the Report of Rapporteur Evans should be rejected.**

3. ANNEX IV: NEW RESTRICTIONS – NANOMATERIALS

Concerns:

- Orgalime does not per se object to new substance restrictions. However, such new restrictions need to be scientifically evaluated beforehand and ensure that the shift to alternatives provides better performance in environmental and technical terms.
- New restrictions would also need to fully tie in with the new European wide EU chemicals regime REACH to avoid undesired environmental results and other negative impacts, such as on product safety or reliability.
- Nanomaterials, which are used in wide ranges of different applications far beyond the electrical and electronics industry, are already covered by the REACH Regulation. The Committee, however, proposes an immediate ban of nano-silver and nano-tubes in RoHS, without impact assessment and without scientific evaluation. In addition, it proposes an inappropriate definition of "nanomaterials" and suggests establishing notification and labelling requirements for all nanomaterials in electrical and electronic equipment. Blacklisting potential technological developments in electrical and electronic equipment alone, in the absence of scientific justification, risk assessment or impact assessment, is just incomprehensible to us, in particular as companies have made investments to explore the potential benefits that the use of nanomaterials can bring, e.g.: for realising the EU's energy and climate change objectives.

Proposals:

- **Support EP amendments 7 and 18 of the Report of Rapporteur Evans**
- **Reject EP amendments 5, 6, 15, 37, 38, 52 of the Report of Rapporteur Evans**

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- **Stick with Commission proposal/Council proposal of 21 May 2010 for annex IV**

4. RoHS EXEMPTIONS

Concerns:

- Orgalime supports improving the criteria and procedure for granting exemptions to established RoHS restrictions. In particular:
  - these should include the socio economic criterion and the criteria of availability and reliability of substitutes. These are accepted criteria under the REACH Regulation and they are important, since phasing out a substance when either its environmental benefits will not outweigh the negative socio economic consequences, or when alternatives are not available or reliable is in our view not a sustainable way forward.
  - introducing a format for applying for exemptions and for the consultation of stakeholders as well as deadlines for the Commission for taking decisions will improve the transparency and legal certainty of the process besides facilitate the preparation for RoHS compliance in companies.
  - Consulting stakeholders during the process will increase transparency and provide necessary technical input.
- Industry remains concerned with "one size fits all" maximum validity periods for all exemptions and prefers a case-by-case approach, which would allow setting appropriate duration periods for each exemption according to the specificity of products and product cycles as well as for clearing complex global supply chains.
- In contrast to the Commission proposal and preceding ERA Technology study report, EP amendment 51.3.e challenges the applicability of the existing RoHS exemptions listed in annex V of the Commission proposal for categories 8 and 9. The ERA report (see table 44 on page 158) lists the existing exemptions of annex V, which are also of relevance for categories 8 and 9. Therefore, the exemptions listed in annex VI should come in addition to the necessary exemptions of annex V for categories 8 and 9, however, not instead of them. Also, the headline of annex V of the Commission proposal does not restrict the application of annex V to any product category.

Proposals:

- **Maintain Commission proposal for article 5.1, 5.3 and 5.4**
- **Support Council proposal of 21 May 2010 for art. 5.2a, 5.2b and 5.2c**
- **Support EP amendments 14, 51** (except 51.1.a. second and third indents, 51.2. first and second paragraphs, 51.3.a and 51.3.e) **and amendments 90 - 100 of the Report of Rapporteur Evans**
- **Reject EP amendments 13 and 51.1a. second and third indents, 51.2. first and second paragraphs, 51.3.a and 51.3.e of the Report of Rapporteur Evans**
- **Support the necessary exemptions of annex V as outlined in ERA Technology report also for categories 8 and 9**

5. RoHS EXEMPTIONS and REACH AUTHORISATIONS

Concerns:

- The EP Environment Committee report and the Council document of 21 May 2010 propose to delete article 5.4 of the Commission proposal, which specifies that, for existing RoHS exemptions and finally approved future RoHS exemptions, no REACH authorisations would have to be sought. We object to the proposal to delete article 5.4, since it would require companies to seek -for the same application of the same substance - a RoHS exemption as

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well as a REACH authorisation. The proposal therefore results in an unnecessary duplication of law.

- In addition, there still remain some uncertainties and possible risks of overlapping requirements to be fulfilled by producers of electrical and electronic equipment considering that the substances listed for assessment in annex III of the RoHS recast proposal are already included in the REACH candidate list for evaluation and are likely to be included in the future REACH annex XIV list of substances to be authorised, too. Restrictions for these very same substances could also be adopted under REACH soon. Since requirements on REACH authorisation will enter into force earlier than a recast RoHS Directive, it remains unclear today how far authorisations granted under REACH would account as possible exemptions under RoHS.
- Finally, the European Parliament proposes via amendment 55 a new article 6.b with the objective to carry over REACH restrictions and phase outs under REACH authorisation into the RoHS Directive. We generally support the proposal, however, it overlooks that the REACH Regulation foresees a number of exemptions from REACH authorisation procedures (i.e.: for certain applications which can be listed specifically in REACH annex XIV, or for uses of annex XIV substances in medical devices according to REACH article 60.2). The proposed amendment could therefore result in the situation that certain uses are exempted from REACH authorisation (and would therefore be allowed under REACH without requesting a REACH authorisation), but would be restricted under RoHS, since there would be no explicit REACH authorisation. These REACH exemptions from authorisation should equally be carried over into RoHS.

Proposals:

- **Maintain Commission proposal for article 5.4**
- **Support EP amendments 55 of the Report of Rapporteur Evans in principle, however, add that the new article 6.b would not apply for uses exempted from REACH authorisation under Regulation (EC) No 1907/2006 (REACH).**
- **Introduce a new article 5.5 which should read as follows**: "*As long as the use of a substance is authorised in accordance with Regulation (EC) No 1907/2006, such equipment shall be considered compliant with the requirements set out in this directive for the validity period of the granted authorisation under Regulation (EC) No 1907/2006."*

6. ALIGNMENT WITH NEW LEGISLATIVE FRAMEWORK (NLF)

Concerns:

- A number of modifications introduced by the Environment Committee outrule the New Legislative Framework (NLF), even though the recast has been announced as the opportunity to also strive for better consistency in this field. Notably, the following proposals are examples of a counterproductive cut off of RoHS from the NLF:
  - The strongly diminished role for European standardisation and instead an increased mandate for the Commission to adopt technical details of RoHS compliance via delegated acts: It is a fundamental principle of the NLF/New Approach, that essential requirements are laid down in the legislation itself but that technical details are left to standardisation with involvement of technical experts. The recast RoHS Directive will include all essential requirements (i.e.: the substance restrictions, their reference level of "homogeneous material" and the tolerated maximum concentration value) in the legal body of the Directive. However, it is now proposed that the technical details, such as for sampling or formats for material declarations, should be adopted via delegated acts, which do not foresee any involvement of technical experts. This does not make sense.

- In addition, standardisation work on RoHS has been ongoing for a long time: New IEC standards have recently been released or are in the process of being released (e.g.: IEC 62476 on "Guidance for the evaluation of products with respect to substance-use restrictions in electrical and electronic equipment"; IEC 62596 on "Electrotechnical products – Determination of restricted substances – Sampling procedure – Guidelines"; IEC 62321 on "Electrotechnical products – Determination of levels of six regulated substances" or IEC 62474 on harmonised formats for material declarations). This work should be fully taken into account for the implementation process of the future recast RoHS Directive.
  In particular, it is important that when developing European harmonised standards, such international standards are taken up in European harmonised standards to facilitate the implementation of substance restrictions in the EEE sector and to avoid unnecessary administrative burden.
- The deletion of the key concept of the CE marking to give presumption of conformity also undermines a core concept of the NLF.
- A definition of "manufacturer" that would depart from the NLF Model Decision 768/2008, as proposed by the EP, could render the distinction between the different economic operators more difficult, weaken legal certainty and thereby open loopholes for free riding. We believe that the definitions of the different economic operators should apply as proposed in NLF Decision 768/2008.

Proposals:

- **Support EP amendments 28-31, 78 and 81 of the Report of Rapporteur Evans**
- **Reject EP amendment 27, 53 and 77 of the Report of Rapporteur Evans**
- **Maintain Commission proposal for article 16, first paragraph**, which reads: *"Member Sates shall presume EEE bearing the CE marking as conforming to the Directive."*

7. ESTABLISHMENT OF A CONSULTATION FORUM

Involving stakeholders in the process of implementing the directive will improve transparency, especially considering that many issues are supposed to be established via comitology, besides contributing to gather technical expertise and know-how that will be essential to facilitating the practical implementation of the Directive and the operations of market surveillance authorities.

Proposal:

- **Support EP amendment 81 of the Report of Rapporteur Evans**