ORGALIME

Position Paper

Brussels, 13 February 2008

Policy options for the review of Directive 2002/95/EC (RoHS)

ORGALIME thanks the Commission for consulting stakeholders on a set of policy options currently under consideration and herewith provides its contribution to the debate. Following some general principles, ORGALIME's comments are structured according to the five basic headings given in DG Environment's consultation paper. Under each chapter heading, ORGALIME provides its views on the various policy options proposed in the Commission's consultation document, but also adds its proposals for alternative options not included in the consultation document but considered relevant by our industries.

A. GENERAL PRINCIPLES

The surroundings of the RoHS Directive today differ significantly from the legislative environment situation at the time of adopting the Directives. In particular, other legislative initiatives that impact the RoHS Directive have in the meantime been finally approved by EU regulators, notably the regulation 1907/2006 on the registration, evaluation and authorisation of chemicals (REACH) and Directive 2005/32/EC establishing a framework for the setting of eco design requirements for energy using products (EuP). Also, the Commission has meanwhile tabled its proposal for the Marketing of Goods (COM(2007)37 and 53), which is currently negotiated between European regulators.

In the light of these developments and the EU's Better Regulation and Simplification policy, the RoHS review should, in our view, be the **transition path of merging RoHS into the newly established REACH regulation** and, in this context, be used as the opportunity to streamline RoHS to the maximum extent possible, going towards achieving **consistency with REACH, EuP and the Marketing of Goods Package:**

- As far as the **existing** RoHS Directive is concerned, the RoHS Directive, as clarified in REACH Implementation Project 3.8, continues to apply. ORGALIME supports this.
- For the **existing** RoHS Directive, ORGALIME encourages the Commission to take any measures needed to ensure a harmonised transposition in member states. A future transformation into REACH would foster further harmonisation considering that the legal character of REACH is a regulation rather than an EC Directive.
- A reference to the harmonised definitions of the Marketing of Goods Package, which are relevant for the existing RoHS Directive (i.e.: put on the market or manufacturer, importer, etc.), should be taken up.
- However, as far as hazardous substances not covered by the RoHS Directive today are concerned, ORGALIME takes the view that the RoHS Directive should no longer be applied, i.e.: it should be "phased out" and **any new restrictions** of substances not included under RoHS today **should be carried out under the REACH regulation**.

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 some 10.6 million people in the EU and in 2006 accounted for some €1,779 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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- Any further new substance restriction in EEE should follow a **risk based approach** (hazard plus exposure) instead of the present hazard based RoHS scope. We consider a risk assessment a pre-condition for any extension of the present scope of substance restrictions in EEE.
- If other EC legislation applying on EEE proposes to have restrictions of the use of specific substances, as it could arise under the implementation process to Directive 2005/32/EC on Eco Design of Energy Using Products, the specific restriction legislation should be adopted under REACH, too. Therefore, when considering introducing new restrictions for substances in EEE, the subsequent restriction legislation should be done under REACH taking into account the EuP Directive and its implementation process.

B. DETAILED COMMENTS ON 5 HEADINGS & OPTIONS OF CONSULTATION DOCUMENT AND ORGALIME PROPOSALS FOR ALTERNATIVE OPTIONS

I. Are further product groups to be included in the RoHS Directive (art. 6 RoHS)?

Regarding the topic of possible product groups to be included into RoHS, and categories 8 and 9 particularly, ORGALIME is aware that the Directive includes a review clause for these categories. However, before considering introducing new restrictions in EEE, e.g.: categories 8 or 9, ORGALIME believes that the uncertainties that today still exist with the present text of the Directive should be solved.

As for categories 8 and 9, one essential characteristic of these types of products is high reliability. This could be affected detrimentally if these categories were to be included in the scope of RoHS at too early a date. In addition, sufficient time is required for testing, validation, trials and obtaining approvals.
Manufacturers of category 8 and 9 equipment typically produce a very large range of technically complex products and each product is sold in relatively small numbers. Many of these products are safety critical and so require lengthy testing and approval by Notified Bodies after any modifications are made.

For categories 8 and 9, ORGALIME generally supports the final report of ERA Technology. At the same time, we underline the necessity that, for certain applications, the substances restricted under RoHS today will still be necessary in the future.

I.1: ORGALIME supports this option. ORGALIME stresses that there is insufficient evidence that the inclusion of categories 8 and 9 will bring significant environmental benefits (see also UNU-EHS study report). An evaluation under a life cycle perspective is needed. Including category 8 and 9 equipment risks compromising product reliability and patient/customer safety. Also, voluntary standards do exist, such as IEC 60601-1-9 on environmentally conscious design of medical electrical equipment.
I.2: ORGALIME supports this option. We underline that there is no evidence supporting the claim that there are "several categories of medical devices and monitor and control instruments which are sold in small quantities but may be relevant for their hazardous substance content". An evaluation should be run under a life cycle perspective.
I.3: ORGALIME does not support this option. Technical adaptation requires reasonable timelines. Considering the wide range, thousands of different products that could fall into these categories a unique date for entry into force appears unrealistic if not creating excessive costs and the risks of reliability performance and patient/customer safety. Moreover the environmental benefit of such a proposal is not proven to date.
I.4: ORGALIME supports this option provided that the assessment from a life cycle perspective demonstrates its environmental benefit.
I.5: ORGALIME generally supports this option, while however preferring option 6. Further exemptions will be necessary.

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I.6: ORGALIME generally supports this option. According to the results of a previous study on lead free solders (EPA), however, we believe the environmental impact of lead free solders should be assessed before deciding for exemptions or inclusions. We feel that such an assessment will confirm the need for specific exemptions for "lead in solders".

I.7: ORGALIME does not support this option. As it is not yet clear which type of products fall under this category, it is not advisable to differentiate between domestic and industrial (there are also dual use products). Domestic products could be as safety critical as industrial ones. This is too complex to be applied in practice and bears the high risk of additional grey areas to occur.

I.8: ORGALIME does not support this option. We believe that there is no evidence for claiming that "RoHS like legislation is spreading around the world and is likely to include these products". China has adopted a different approach including IT sectors "only". The Governor of California, on 13th October 2007, refused to expand the scope of RoHS for the following reasons that we support:

> *"- the approach taken by the bill is largely unworkable and will result in unintended and potentially more harmful consequences.*
>
> *- the language for exempting spare parts and refurbished products deviates from the EU Directive and will make many electronic products prematurely obsolete, forcing their retirement years earlier than necessary.*
>
> *- the bill is overly broad in scope and will prohibit the sale of potentially tens of thousands of electrical and electronic products for California's consumers and businesses."*

ORGALIME proposes the following alternative options:

- Take **any measure to harmonise transpositions** in member states
- An **explicit clarification of the intended scope of these categories by setting criteria**, explaining what is included and, equally important, which types of product would be excluded, before imposing substance restrictions on category 8 and 9 equipment.
- **No restriction should be imposed for the following non exhaustive list of examples of substances in certain applications in categories 8 and 9:**
  - Lead and cadmium for specific electrical inter-connections
  - Lead for radiation shielding
  - Lead for high mass applications (e.g.: phantoms and counterweights)
  - Lead for thermal management
  - Lead, cadmium, hexavalent chromium & mercury used for sensing & detection
  - Lead in piezoelectric crystals for diagnostic ultrasound transducers
  - Plating finishes on lead less devices, e.g.: BGAs, CSPs, WLCSP, QFN
  - Lead oxide containing glass used in X-Ray tubes (as vacuum adhesives)
  - Lead in solders in portable emergency defibrillators, active implantable medical devices, MRI radio frequency coils and IVD optocouplers
  - Lead in alloys to improve material properties in specific applications
  - Lead for radiation shielding in radioactivity measurement and detection equipment
  - Lead, mercury and cadmium in sensors, detectors and electrodes used in Category 8 and 9 equipment
- The **European Commission should take advice from Notified Bodies** on whether the field data available is sufficient to ensure that use of lead-free solder will enable cat. 8 and 9 equipment to meet the essential safety and performance requirements in the relevant Directive. If the Notified Bodies' opinion is that the field data available is not sufficient to confirm reliability of long-term use of lead-free soldering in safety critical applications, then the European Commission should not impose substance restrictions until such time as adequate field data does become available. Therefore, **dates for imposing any substance restrictions on categories 8 and 9** have to take this into account, too.

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II. SUBSTANCES COVERED

Regarding the substances covered by the RoHS Directive (Articles 4 and 6 RoHS), the review should investigate the effects and burdens at a global scale and the relevance of electrical and electronic industry, especially with regard to an international standardisation/harmonisation.

In principle, article 4 RoHS calls for a "zero level" of the mentioned substances. However, this is impossible to be implemented, since in practice certain concentrations, such as traces and impurities, are ubiquitous, therefore also unavoidable in EEE. The present RoHS Directive therefore allows in article 5.1.a, the establishment of tolerated maximum concentration values of the concerned substances. Orgalime advocates that any further substance restrictions in EEE also acknowledge this reality and continues allowing tolerance margins in a legally binding way.

II.1 ORGALIME supports this option. It would foster consistency and coherence of EU legislation and increase legal certainty for companies. As far as substances not covered by RoHS Directive today are concerned, ORGALIME takes the view that the RoHS Directive should no longer be applied, i.e.: it should be "phased out" and any new restrictions of substances in articles not included under RoHS today should be carried out under the REACH regulation.
II.2 ORGALIME does not support this option. When considering introducing new restrictions in EEE, the subsequent legislation should be done under REACH.
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II.4 ORGALIME does not support this option. When considering introducing new restrictions in EEE, the subsequent legislation should be done under REACH.
II.5 ORGALIME supports this option. We believe that new substances should only be regulated if substitutes are already available and investigated but when considering introducing new restrictions in EEE, the subsequent legislation should be done under REACH.
II.6 ORGALIME does not support this option. When considering introducing new restrictions in EEE, the subsequent legislation should be done under REACH.
II.7 ORGALIME does not support this option. When considering introducing new legislative requirements, this should be done under REACH.
II.8 ORGALIME does not support this option since it could hamper innovation in recycling technologies. Such an option could be evaluated case by case under the EUP framework, not in a general horizontal measure.

III. TECHNICAL CHANGES TO THE SCOPE OF THE DIRECTIVE

ORGALIME seeks the de-coupling of the scopes of RoHS and WEEE and the codification of an own scope for the existing RoHS Directive. It is inconsistent for RoHS to refer to the scope of WEEE, and the categories listed in the WEEE Directive more particularly, since RoHS is an article 95 Directive, while WEEE is based on article 175.

ORGALIME notices confusion in the application of article 2.1 WEEE and the Commission's guidelines on "fixed installations" and "finished products" as given in the F.A.Q.s of May 2005 for the RoHS Directive. ORGALIME fully supports the Commission's view expressed in the F.A.Q.s.

The notion "fixed installation" is a settled term that is derived from existing Community law, notably in article 2.c of Directive 2004/108/EC on Electromagnetic Compatibility. If fixed installations were considered to fall under the scope of RoHS, as some seem to argue, this would mean that installations in petrochemical, automobile manufacturing, pharmaceutical, material handling, power generation, water treatment or paper manufacturing plants would be subject to RoHS. This clearly was neither the intention of the WEEE Directive and even less the intention of the RoHS Directive when they were adopted.

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Article 2.1 WEEE refers to all categories listed in annex I.A of the WEEE Directive. The criterion of "another type of equipment" and its additional interpretation guideline of "fixed installations" therefore cannot be limited to a selected number of WEEE categories. For RoHS, it should be horizontally applied as a criterion on its own right. It should therefore be handled completely separately from the exclusion of "large-scale stationary industrial tools" as listed in category 6 of Annex IA/IB of the WEEE Directive.

III.1 ORGALIME supports this option. It is inconsistent for RoHS to refer to the scope of WEEE, since RoHS is an Article 95 Directive, while WEEE is based on Article 175.
III.2 ORGALIME does not support this option. Explicitly including spare parts and components would modify the scope and thereby change the fundamental principle of RoHS that it applies on finished products. For spare parts, it is unnecessary to provide a separate definition since in the context of other relevant Directives sufficient clarification is given, e.g.: Blue Guide for New Approach, and there are no requests for further legal clarification on this field.
III.3 ORGALIME supports this option. The criterion of "another type of equipment" should be applied as a criterion on its own right because it never was in the intention of the RoHS Directive to include installations, such as in petrochemical, automobile manufacturing, pharmaceutical, material handling, power generation, water treatment or paper manufacturing plants in the RoHS Directive. This option is in line with the Commission's FAQ's of May 2005, which we support. The UNU-EHS study challenges that environmental benefits can justify the inclusion of B2B equipment.
III.4 ORGALIME supports this option as the non- inclusion of article 2.3 WEEE in the legal text of RoHS was an editorial default only.
III.5 ORGALIME does not support this option since it would lead to the discriminating situation that consumables supplied with the product would be considered inside the scope, while consumables delivered separately would not require RoHS compliance. Following the Commission's FAQ's of May 2005 (page 11), the RoHS Directive does not apply to consumables, e.g.: ink cartridges. This we support. REACH is addressing this issue.
III.6 ORGALIME does not support this option. The UNU-EHS study concludes that the environmental benefits cannot justify the inclusion of B2B equipment.
III.7 ORGALIME does not support this option. The general exemption of Large Scale Industrial Tools should continue to apply. The UNU-EHS study challenges that environmental benefits can justify the inclusion of B2B equipment.
III.8 ORGALIME does not support this option. When considering introducing new restrictions on new product groups, the subsequent legislation should be done under REACH taking into account the EuP Directive and its implementation process.
III.9 ORGALIME does not support this option. Instead of an indicative list, which can never be complete, clear criteria are needed to provide legal certainty. Indicative lists risk further fragmentation in the internal market.
III.10 ORGALIME supports this option. It would increase legal certainty and be beneficial for environment since unnecessary scrapping of existing appliances would be avoided.

ORGALIME proposes the following alternative option:

- **Clarify the relationship between the WEEE and RoHS Directives by amending the RoHS Directive with an own scope that incorporates article 2.1 WEEE ("another type of equipment" and the definition of "fixed installation" as provided in article 2.c of Directive 2004/108/EC on Electromagnetic Compatibility into the legal text of the RoHS Directive**

IV. DEFINITIONS

ORGALIME stresses that the use of the term "homogeneous material" creates severe problems concerning compliance with the RoHS Directive and fair competition, since it is undefined and moreover principally not rigorously definable. Generally, the only well defined reference can only

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be the article as placed on the market or, as in the case of the flame retardants, the material treated with or containing the substances as it is done in Directive 76/769/EEC.

In addition, the definition provided in the Commission's FAQs of May 2005 is inconsistent with article 5.1b RoHS, which refers to "establishing, as necessary, maximum concentration values up to which the presence of the substances referred to in Article 4(1) in specific materials and components of electrical and electronic equipment shall be tolerated".

The concept of 'homogeneous material' is creating practical problems, when employing test methods. Demonstrating compliance by requiring testing would mandate testing up to thousands of different homogeneous materials for one single product. Moreover, with the advent of REACH, the concept of homogeneous material may become more confusing since REACH requires notification of certain substances, but at the article level.

When reviewing the procedures for market surveillance, it is essential that Europe supports the ongoing work at the international level, such as at IEC, since electrical and electronic equipment manufacturers act on highly competitive global markets.

IV.1 ORGALIME supports this option provided that the definition is a reference to the Marketing of Goods Package.
IV.2 ORGALIME supports this option provided that the definition is a reference to the Marketing of Goods Package.
IV.3 ORGALIME supports this option provided that such a definition is identical to the definition given in article 2.c of Directive 2004/108/EC on Electromagnetic Compatibility.
IV.4 ORGALIME supports this option. The intended scope of categories 8 and 9 by setting criteria, explaining what is included and, equally important, which types of product would be excluded, should be explicitly clarified before imposing substance restrictions on these categories of equipment.
IV.5 ORGALIME does not support this option. Instead of an indicative list, which can never be complete, clear criteria are needed to provide legal certainty. Indicative lists risk further fragmentation in the internal market.
IV.6 ORGALIME believes that the definition of "homogeneous material" provided in the FAQ document may be used as a starting point, but it will require clarification in view of practicability (see comments above). ORGALIME does not object an inclusion of the level of MCVs in the legal text of the RoHS Directive, though notes that these are meanwhile laid down in a legally binding Commission decision.
IV.7 ORGALIME does not support this option. It is unnecessary to provide such a separate definition since in the context of other relevant Directives sufficient clarification is given, e.g.: Blue Guide for New Approach.

ORGALIME proposes the following alternative options:

- **Include a** reference to Marketing of Goods Package for definitions **of "put on the market" and economic operators relevant in the legal text of the RoHS Directive (instead of including definitions themselves in the legal text of the RoHS Directive).**
- Take up the work that is carried out in international standardisation processes, **such as IEC standard on procedures for determining the levels of regulated substances in electro technical products.**

V. FACILITATING IMPLEMENTATION

Although the RoHS Directive is an Article 95 Directive, the lack of enforcement procedures potentially leads to Member States enforcing RoHS differently, which subsequently does not create a 'level playing field' across Member States. Therefore, more consistent and effective enforcement should be put in place:

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RoHS is not a New Approach Directive. However, ORGALIME supports for all areas of market surveillance and enforcement that the principles of the New Approach should be applied, i.e.: presumption of conformity and harmonised standards for test methods.
However, ORGALIME recommends not shifting RoHS into a New Approach Directive at this stage any longer, e.g.: by including conformity assessment procedures, since the REACH regulation is not a New Approach regulation.

According to Directive 2001/95/EC on General Product Safety, the RAPEX system for the purpose of consumer protection and human health already applies. Therefore, ORGALIME does not see the need for a separate entry in the RoHS Directive.

Regarding the present exemptions mechanism foreseen in article 5.1.b of the RoHS Directive, ORGALIME requests the Commission to cover technical, economic and international implications when analysing exemption requests in order to ensure that any proposal is feasible. The existing exemption mechanism has shown being too lengthy, complex and burdensome a process. ORGALIME therefore generally supports improving the workability of the existing exemptions mechanism in terms of speed, cost efficiency and more clear and transparent criteria.

Va.1 ORGALIME supports this option. ORGALIME supports for all areas of market surveillance and enforcement that the principles of the New Approach should be applied, i.e.: presumption of conformity and harmonised standards for test methods.
Va.2 ORGALIME does not support his option. RoHS should not be shifted into a New Approach Directive at this stage any longer, since the REACH regulation is not a New Approach regulation.
Va.3 ORGALIME does not support his option. The REACH regulation should apply. Too many different and overlapping labelling requirements are confusing for consumers.
Va.4 ORGALIME does not support his option. According to Directive 2001/95/EC on General Product Safety, the RAPEX system for the purpose of consumer protection and human health already applies. Therefore, ORGALIME does not see the need for a separate entry in the RoHS Directive.
Va.5 While **ORGALIME supports the use of international standards,** material databases and material declaration formats would impose too heavy administrative burden for companies, especially SMEs.
Va.6 No particular view.
Va.7 ORGALIME does not support this option. The RoHS Directive already includes a review obligation of granted exemptions at least every four years after the item has been added to the RoHS annex. For any new substance restrictions, REACH should apply.
Va.8 ORGALIME supports this option. It would increase transparency and facilitate information gathering while at the same time foster consistency with EuP Directive.
Va.9 ORGALIME does not support this option. It risks creating an additional, inefficient and diverted administrative burden.

Vb.1 ORGALIME does not support this option since companies have made significant investments to comply with the RoHS Directive. Reducing the scope at this moment in time would hamper the implementation process and penalise the EEE industry for its proactive work.
Vb.2 ORGALIME does not support this option. The stakeholder mechanism shall be improved (see option Va.8), however neither be reduced nor removed.
Vb.3 ORGALIME does not support this option. Product legislation should ensure that same requirements apply for same products. However, it should not lead to discrimination between competing technologies. Regulators have confirmed the principle of technology neutrality in the EuP Directive.
Vb.4 ORGALIME does not support this option. Article 7 (2) of the RoHS Directive referring to Article 18 of Directive explicitly describes the duty of the Commission to thoroughly evaluate exemption requests according to the Comitology procedure. Relevant

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information need to be provided and assessed in a neutral manner and should not be biased by applicants interests.
Vb.5 ORGALIME does not support this option. It is very unclear which criteria should be applied to potential substitutions. In particular, there are substitutions possible which are not feasible for specific applications or creating disproportionate costs or in certain cases substations may not be feasible at all. For all these cases it would practically not be possible to provide substitution plans.
Vb.6 ORGALIME supports this option since it would better structure the way of making exemption requests and thereby enhance transparency.
Vb.7 ORGALIME supports this option since sustainability requires the integration of economic, environmental and social aspects. The option would enhance consistency with REACH and EuP.
Vb.8 ORGALIME supports this option. Especially, the socio-economic route of REACH should be taken up in the existing RoHS Directive.
Vb.9 ORGALIME does not support this option. Technical analysis, impact and risk assessments shall be carried out by the responsible technical expert bodies. Regulators should remain responsible for taking the political decision. ORGALIME would, however, support an improved link between the TAC and the stakeholder(s) requesting an exemption, such as proposed in option Va.8, which we support.

ORGALIME proposes the following alternative options:
- Take **any measures needed to harmonise transpositions** in member states
- **Introduce a deadline** to apply for the Commission (and TAC) to decide on an exemption request. No response within the time period should mean that the exemption is granted (may be on a reviewed timeframe).
- **Apply REACH regulation for any future restrictions:** Fosters legal consistency and coherence

C. CONCLUSIONS

ORGALIME underlines the need to better streamline existing EC legislation that applies on electrical and electronic equipment at the same time, and the RoHS Directive, the REACH regulation, the EuP Directive and Marketing of Goods package more particularly. The RoHS review is an opportunity to do so, especially by clarifying that the REACH regulation should apply -instead of the RoHS Directive- for any future restrictions of substance not covered by RoHS today.

For the upcoming review of the RoHS Directive, ORGALIME does not support options that would run counter the principle of Better Regulation and Simplification or result in unnecessary additional administrative burden or costs on companies, many of which are SMEs. This would in our view be particularly the case if options I.3, II.2-II.4, II.7, II.8, III.6, III.8, III.9, IV.5 or Va.3 were chosen for the way forward.

For the existing RoHS Directive that would continue to apply, however, the review should be used as an opportunity to improve its workability, for example in the areas of the scope, the exemptions mechanism or stakeholder consultation, so as to foster a fully harmonised transposition of the Directive in EU member states.

Proper market surveillance and enforcement are in our view of major relevance to the effectiveness of the Directive both, in terms of its environmental objectives but equally in terms of legal certainty and cost effectiveness for EU manufacturers of electrical and electronic equipment.

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