ORGALIME

Position Paper

Brussels, 30 June 2009

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

COM (2008)809 final

Orgalime kindly requests the support of European regulators for the following comments and proposals for shaping 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):

EXECUTIVE SUMMARY

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. Also, the legislative environment in terms of existing EU law changed considerably since the entry into force of the initial RoHS Directive, which should have been reflected accordingly for the RoHS recast. While we acknowledge some improvements, we feel that the RoHS recast proposal generally fails to realise these objectives, in particular since it continues overlapping with other legislation and thereby creating legal uncertainty.

Consequently, Orgalime's fundamental request to regulators is to ensure full legal consistency between the RoHS Directive and other legislative initiatives that have been finalised after the adoption of the initial RoHS Directive. More particularly, Orgalime asks for:

- **CONSISTENCY WITH REACH**

  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 all REACH criteria and procedural elements for establishing any further substance restrictions in EEE.** This has to particularly include the full application of articles 68-73 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 process of establishing substance restrictions.

- **CONSISTENCY WITH NEW LEGISLATIVE FRAMEWORK (NLF)**

  We welcome the proposal to introduce the NLF into the recast RoHS Directive 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 some 11.1 million people in the EU and in 2008 accounted for some €1,885 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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- **CONSISTENCY WITH OTHER ENVIRONMENTAL PRODUCT LEGISLATION**

  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 and especially the preparatory study process to Directive 2005/32/EC on Eco Design of Energy Using Products, the specific substance restriction legislation should be adopted in accordance with REACH title VIII, too.

- **A WORKABLE AND REALISTIC EXEMPTIONS MECHANISM**

  Orgalime advocates for an improvement of the existing exemptions mechanism, and in particular for **consistent criteria, realistic timelines for initiating a review of exemptions on a case by case basis, as well as the possibility to grant a transition period in cases of a definite expiry of an exemption.** We are particularly 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.

  We also believe that **a new Consultation Forum should be created** to ensure a continuous and structured consultation mechanism in the implementation process of the directive.

  Finally, a **deadline for the Commission to take a decision on an application for an exemption** would be helpful.

- **A TRULY HARMONISED SCOPE ESTABLISHED IN THE RoHS DIRECTIVE ITSELF**

  Orgalime welcomes the **proposal to explicitly define the scope of the RoHS Directive directly in the RoHS Directive itself**. So far, member states' interpretations on what products would fall under the directive's scope in their country have been somewhat diverging. However, the proposed new annexes I and II remain unclear and should be clarified in the interest of a fully harmonised scope.

  Orgalime does also in principle not oppose 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.

- **A RECAST THAT SECURES THE GLOBAL COMPETITIVENESS OF EU MANUFACTURERS OF ELECTRICAL AND ELECTRONIC EQUIPMENT**

We call upon on the European Parliament and the Council to take our comments, which are further substantiated in the below chapters, into account in the further proceedings.
We look forward to providing further input to the legislator.

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I. INTRODUCTION

Orgalime and its European manufacturers of electrical and electronic equipment are fully committed to continuously improve the environment performance of products throughout their life cycle, including the use of substances and related end of life aspects.

Since its adoption in 2003, Orgalime industries have gathered the following main experiences with the implementation of the RoHS directive:

- Product requirements in our view have to be unambiguous, clear and harmonised. Despite a legal base of article 95 of the EC Treaty, Member States transposition process of the RoHS Directive, however, has led to a significant number of diverging implementations and interpretations, e.g.: in the areas of scope, exemptions or compliance. This has inevitably caused negative impacts on the functioning of the internal market for EEE, difficulties for manufacturers to apply the law in practice, uncertainties for enforcement in member states and thereby facilitate unfair competition.
- The comitology process through the Technical Adaptation Committee has often been a "closed shop", discussing technical issues that affect manufacturers directly in an intransparent manner, besides taking decisions at a very late stage. Also, the criteria and procedures for its activities have not always been transparent. This has often caused delays of important decisions and left manufacturers facing uncertainty, while compliance deadlines were approaching quickly making manufacturers face tight timescales for clearing supply chains.
- At the same time, timelines for implementing the phase out of RoHS restricted substances should have been more realistic to ensure compliance without compromising the functionality, fitness for purpose or safety of the product.
- Other regions of the world have taken action on substances used in EEE, too, however, with only limited coordination between the different regions of the world. Producers are active in international standardisation organisations to help developing as harmonised as possible a level playing field in the area of substance restrictions across the different regions of the world.

Most important at this stage of the RoHS recast, however, is the fact that **the legislative environment in terms of existing EU law has changed considerably since the entry into force of the initial RoHS Directive**. In particular, the following other legislative initiatives that directly impact the RoHS directive have been finally approved by the EU regulators in the meantime:

- **Regulation 1907/2006** on the registration, evaluation and authorisation of chemicals (**REACH**)
- **Directive 2005/32/EC** establishing a framework for the setting of eco design requirements for energy using products (**Eco Design Directive**)
- **Decision 768/2008** - The EU's **New Legislative Framework** (formerly Marketing of Goods Package)

In the light of these developments and the EU's Better Regulation and Simplification agenda, **Orgalime supports the goal of the RoHS recast to establish full consistency between these legislative acts**.

Orgalime sees a number of improvements introduced by the Commission RoHS recast proposal that aim at striving for such better consistency. However, Orgalime is concerned that despite the stated aim of ensuring full consistency, this has not been entirely achieved. This is particularly evident in the following areas:

- The evaluation process of substances that are under consideration for restriction in EEE in the future in the light of the newly created EU wide harmonised REACH Regulation
- The process and criteria for granting RoHS exemptions
- Clear mandates for standardisation organisations for RoHS compliance
- Market surveillance and strong enforcement rules, such as "Safeguard procedures" concerning member states' actions with regards to non compliant products in line with the NLF

The subsequent chapters specify our main concerns in more detail and propose alternative ways forward, for which we seek the support of regulators in their further proceedings.

II. CONSISTENCY WITH REACH

The REACH Regulation provides the EU's harmonised framework for registering, evaluating, restricting and authorising chemicals and their uses in the EU. The electrical and electronics industry sector has not been excluded from this regulation.

In particular, title VIII of REACH concerning "restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles" treads into the field of the RoHS Directive. Certain overlaps could also occur with title VII REACH on authorisation of the use of certain substances for the manufacturing of electrical and electronic appliances (i.e.: the candidate list for substances to be authorised already includes the four substances proposed for assessment in annex III of the RoHS recast proposal).

We would like to draw your attention to the following important comparative notes between RoHS and REACH to avoid misunderstandings:

- While REACH *registration* requirements do indeed enter into force step by step depending on tonnage volume bands of a substance, there are **no tonnage thresholds for applying REACH restriction or authorisation requirements**. These can therefore be established independently from any volume of a substance, as it is the case today with the RoHS Directive.
- **REACH title VIII on restrictions enters into force on 1.06.2009**, therefore earlier than a recast RoHS Directive. Also, member states can initiate a restriction procedure under REACH, while for RoHS the right of initiative remains with the Commission "solely". Member States can initiate REACH restriction processes as of 1.06.2009. Furthermore, the now proposed process of developing a separate RoHS methodology for substance restrictions would consume additional time.
- **It is NOT a precondition for establishing REACH restrictions that the substance would have to be listed on the REACH candidate list first.** Any substance can be targeted for restriction In accordance with the procedure and criteria of title VIII REACH.
- The restrictions of the RoHS Directive can be established at an equally ambitious level within REACH.
- REACH restrictions are substance based, i.e.: REACH evaluates and assesses **any substance of concern in any of its applications** also beyond the EEE sector, thereby reducing potential negative supply chain implications. RoHS, however, looks at the application of a given substance in solely one area of application, namely in electrical and electronic equipment. This is not logical.
- **Under REACH, the risks related to a substance are evaluated and assessed from a life cycle perspective, including the end of life phase,** before establishing substance restrictions. RoHS, however, does not follow a life cycle approach.

For details, please see annex: "**ORGALIME working document comparing the process and criteria of establishing substance restrictions under RoHS and under REACH**"

1. The recast offers the opportunity to remove unnecessary overlaps in legislation

Today, the electrical and electronics industry sector is included in both, the scope of the RoHS Directive and the scope of the REACH Regulation. Both, REACH and RoHS, claim to lay down the rules for the restriction of substances. RoHS claims to do so for electrical and electronic equipment. The scope of REACH is broader and regulates substance restrictions for a broad range of industrial sectors also beyond the EEE sector.

Establishing parallel frameworks for substance restrictions in EEE, however, is neither helpful for the environment, since it easily results in conflicting requirements, nor fair to the industry, since it will have to comply with two different laws while supplying products to all other industrial sectors that have to comply with REACH and bearing the financial and economic consequences of (unnecessary) double legislation. Clarification of the link and relationship between the REACH Regulation and the RoHS Directive is therefore an important matter.

Therefore, it is Orgalime's overall objective that the recast process of the RoHS Directive would remove such overlaps:

Orgalime proposal

- Introduce a new recital that should read as follows: "*A thorough analyses of the added value of the RoHS Directive shall be carried out at the upcoming REACH review with a view to integrating Directive 2002/95/EC (RoHS) into Regulation (EC) No 1907/2006."*
- In the meantime, all criteria and procedural elements for establishing any further substance restrictions in EEE need to be fully in accordance with REACH (i.e.: title VIII on restrictions).

2. Subject matters

Article 1 REACH establishes a threefold objective for substance management in the EU, namely, environmental protection securing the internal market and promoting competitiveness and innovation. The RoHS recast proposal, however, focuses solely on environment protection. Notwithstanding a reference to the internal market in the explanatory memorandum of the RoHS recast proposal, the legal text of the directive does not mention it. Competitiveness and innovation have been ignored in their entirety as a subject matter for RoHS. This is contrary to the stated policy of the EU institutions, which promote sustainability as providing technological advancement and economic benefits.

Orgalime proposal

- Adapt article 1 RoHS as follows: "*The purpose of the directive is to approximate the laws of member states on the restrictions of the use of hazardous substances in electrical and electronic equipment with a view to ensuring a high level of protection of human health and the environment, as well as to ensuring the free circulation of electrical and electronic equipment on the internal market while enhancing competitiveness and innovation*."

3. Criteria and procedures for the evaluation of substances

We acknowledge that a number of REACH elements have been taken into account in the RoHS recast proposal. However, we regret that some fundamental elements of REACH for establishing EU wide substance restrictions have been ignored in the recast proposal. This is particularly the case for the **evaluation process of substances prior to establishing new restrictions of substances used in EEE**:

While REACH assigns particular responsibilities for the evaluation process to the European Chemicals Agency and two (independent) scientific bodies (i.e.: the socio economic committee and the risk assessment committee), the RoHS recast proposal mandates a member states (waste policy) committee to develop, through comitology with scrutiny, "*a methodology for the evaluation of substances based on the process set out in articles 69-72 REACH*" and to adopt final substance restrictions for EEE.

Orgalime cannot see any reason or justification for developing an additional methodology for substance evaluation in EEE if such a methodology already exists in REACH. We also cannot see the added value of two parallel evaluation procedures with multiple studies and different committees being involved. Such double processes risk leading to conflicting requirements.

Orgalime proposal

- All criteria and procedural elements of REACH title VIII shall apply in their entirety for RoHS
- The phrase "*using a methodology based on the process set out in articles 69-72 of the Regulation (EC) No 1907/2006*" in article 4.7 of the RoHS recast proposal shall be replaced:
  - by the words "*according to articles 68-73 of the Regulation (EC) No 1907/2006",* AND
  - by the deletion of the last sentence *of article 4.,* which reads *"Those measures designed to amend.....regulatory procedure with scrutiny referred to in Article 18(2)".*
- Delete recital 6 of the RoHS recast proposal, since the substances listed in annex III are already scheduled for assessment under REACH

4. Relationship between RoHS exemptions and the REACH authorisations

In addition to the restriction processes under RoHS and REACH, the REACH authorisation process is also ongoing. The RoHS recast proposal specifies that for existing RoHS exemptions and finally approved future RoHS exemptions, no REACH authorisations would have to be sought. We welcome this proposal in the light of improving consistency and legal certainty.

However, there still remain some uncertainties and possible risks of overlapping requirements to be fulfilled by producers of EEE considering that the four 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 in how far granted authorisations under REACH would account for possible exemptions from RoHS.

Orgalime proposal

- 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.*"

III. CONSISTENCY WITH OTHER ENVIRONMENTAL PRODUCT LEGISLATION

It is crucial that substance restrictions tie into a holistic approach of a full life cycle perspective of products to avoid both, arbitrary investment requirements to the industry and adverse results for the environment.
For example, the use of mercury in a compact fluorescent lamp results in an increased energy efficiency performance of the lamp in comparison to conventional light bulbs. Decisions on substance restrictions should therefore only be considered after having evaluated the impact of the substance restriction on all other important environmental aspects during the life cycle of the product, such as energy efficiency.

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 and especially the preparatory study process to Directive 2005/32/EC on Eco Design of Energy Using Products, the specific substance restriction legislation should be adopted in accordance with REACH title VIII, too.

Orgalime proposal

- When considering introducing new restrictions for substances in EEE, the subsequent restriction legislation should be done under REACH taking into account the Eco Design Directive and its implementation process.
- The phrase "*which may also be covered by this Directive"* in recital 9 of the RoHS recast proposal should be replaced by "*which may also be covered by EU legislation restricting the use of certain substances in electrical and electronic equipment according to Regulation (EC) No 1907/2006".*

IV. CONSISTENCY WITH THE "NEW LEGISLATIVE FRAMEWORK" (NLF)

The New Legislative Framework (NLF/New Approach), including Decision 768/2008 as a toolbox for regulators, has been created with the objective of achieving better consistency of different EU regulations affecting same products. In particular, electrical and electronic equipment is not only subject to the RoHS Directive, but it is at the same time covered by different pieces of New Approach type legislation (such as the Low Voltage Directive).
Orgalime supports the New Legislative Framework and welcomes the proposal to introduce relevant parts of the NLF/Decision 768/2008 into the recast RoHS Directive.

Promoting the treatment of environmental issues in an integrated manner in companies is a successful tool to move environmental awareness forward in companies. Companies falling under the scope of RoHS in most cases already have proven structures in place driven by the New Approach (now NLF), and it makes sense to use such structures also for the implementation of RoHS. Introducing the NLF into RoHS will improve enforcement and help reducing costs for industry and consumers alike while securing the environmental objectives of the directive.

Orgalime supports that the Commission proposes a uniform mechanism for demonstrating compliance based on the internal production control procedure set out in module A of annex II of Decision 768/2008/EC.

However, there are a number of key areas regarding the introduction of the NLF into the recast RoHS Directive, which would require improvement:

1. A clear mandate for standardisation

Article 6 of the RoHS recast proposal provides that the Commission shall adopt the detailed rules for compliance with the maximum concentration values (MCVs) of article 4(2). However, the recast proposal itself already provides for the essential requirements for RoHS compliance (i.e.: the level of these MCVs per homogeneous material as well as a definition of homogeneous material that applies for all covered product groups at a horizontal level).

Any further technical details should, in line with general principles of the New Approach, be specified through the **establishment of harmonised standards**. Considering that the EEE industry is a globally acting industry, European standardisation work should fully build on already ongoing international standardisation work, including harmonised international standards, technical reports (TR/TS) or public available specifications (PAS).

Article R9 of Decision 768/2008 foresees that a Member State or the Commission can formally object to a harmonised standard in case they do not find it satisfactory. This provision is missing in the RoHS recast proposal and could in our view be introduced.

Orgalime proposal

- The phrase "*detailed rules for*" in Article 6 of the RoHS recast proposal shall be moved from the introductory sentence to the first indent of this article, and the **second indent of Article 6** should be replaced by the following wording: "*mandate European standardisation bodies without delay to develop harmonised standards related to RoHS compliance for each product category listed in annex I. The definition of homogeneous material of article 3.l shall serve as the common base for further specification in standardisation, especially on sample preparation*."
- Introduce a new recital reading as follows: "*For the purpose of enforcement, harmonised standards shall be used. International standards shall be taken into account for harmonised standards in Europe*."
- Introduce article R9 of Decision 768/2008 into the RoHS Directive

Thus, provided that standardisation is finally mandated to develop details of RoHS compliance, our industry supports the inclusion of the levels of tolerated maximum concentration values (MCVs) in annex IV/article 4.2, and a definition of homogeneous material in article 3 of the RoHS directive.

However, the proposed definition of "homogeneous material" would require improvement to provide the necessary clarity and legal certainty for all product categories covered by the directive in line with the Commission's own Guidance Document (FAQs of August 2006).

Also, the title of annex IV of the RoHS recast proposal correctly spells out that it would provide the list of prohibited substances and at the same time the tolerated maximum concentration values (MCVs) for each substance. However, the provision to adopt such MCVs is proposed to be deleted from the directive (see article 5.a). For legal certainty, it is important to reintroduce this provision.

Orgalime proposal
- Rephrase the definition of "homogeneous material" in article 3.l as follows: "*homogeneous material shall mean either a material of uniform composition throughout, or a material that cannot be mechanically disjointed into different materials meaning that the materials cannot be separated by mechanical actions, such as unscrewing, cutting, crushing, grinding or abrasive processes*."
- Reintroduce the requirement to establish the level of MCVs for each restricted substance in article 5 as follows: *"(aa) the level of tolerated maximum concentration value for each substance listed in annex IV*"

2. Introduce all relevant definitions provided in Decision 768/2008/EC into RoHS

Introducing the NLF into RoHS also provides the opportunity to streamline a number of fundamental definitions and administrative requirements regarding products that fall under the scope of several pieces of legislation. We particularly support the introduction of the definitions provided in articles 8-13 of the RoHS recast proposal as well as article 14 on CE marking that are generally consistent with relevant articles of Decision 768/2008/EC.

However, a number of important **definitions** provided in the NLF and of relevance for RoHS have unfortunately not been taken up in the RoHS recast proposal. This should be resolved.

Orgalime proposal:
- Introduce a reference to the definitions of "economic operators", "technical specification", "recall" and "withdrawal" as provided in R.1.7, R1.8, R1.14 and R1.15 of Decision 768/2008/EC in article 3 of the RoHS recast proposal

3. Introduce the relevant NLF- safeguard procedures into RoHS

We also miss a number of relevant requirements of **chapter 5 of Decision No 768/2008 related to "Safeguard procedures",** which addresses Member State actions with regard to non-compliant products. Introducing them, however, would strengthen market surveillance.

Orgalime proposal:
- Introduce a reference to articles R31, R32 and R34 of 768/2008/EC into the RoHS Directive
- Delete last sentence in article 7.9 RoHS

4. Clarify the provision on presumption of conformity

Including a new provision on **presumption of conformity** (article16) in the recast RoHS Directive is, in our view, generally a step in the right direction. However, the wording of article 16 of the RoHS recast proposal is not fully in line with respective wording for such a provision as given in R8 of Decision No 768/2008, nor with the existing member states "EU RoHS Enforcement Authorities Informal Network" guidance.

Product development and manufacturing methods of electrical and electronic equipment must focus on the control of the supply chain of the different components to secure the restriction of the use of certain substances. A company's internal control procedures are generally based on substantiated documentation and communication through the whole supply chain, which is worldwide. The motivation behind this practice is that if one wishes to keep certain substances out of EEE, one needs to ensure that these are never introduced. Substances already included in an appliance, however, cannot be eliminated through a simple design change after having carried out a test. This would be a much more complex process. Therefore, article 16 of the RoHS recast proposal should not be limited to testing and measurement standards.

Orgalime proposal
- Reword article 16 according to article R8 of Decision No 768/2008 as follows:
  "*Electrical and electronic equipment which is in conformity with harmonised standards or parts*

thereof the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with all the relevant requirements of this Directive to which such standards relate."

5. Harmonise market surveillance to the extent possible

To strengthen the environment benefit of the directive and fair competition, it is in our view important to harmonise market surveillance to the extent possible.

Orgalime proposal

- Introduce the requirement to establish a guide on market surveillance building upon the existing member states RoHS enforcement guidance document

6. The introduction of the NLF into RoHS should not result in diverging requirements or double administrative burden – choosing the adequate parts of Decision 768/2008

It is important that the introduction of the NLF into the recast RoHS Directive does not result in having any definition or requirement in two places. Then, the added value would be lost.
It is also important that when regulators decide that RoHS should take up the NLF that the model articles provided in Decision 768/2008 are the fundamental guiding text. Modifications should in principle not take place. If a modification were justified, it needs to preserve the spirit and fundamental principles of the NLF.

Decision 768/2008 is a model decision for legislators. This does not mean that all of its provisions will be relevant for any directive subject to alignment with the NLF, such as the RoHS recast proposal. However, it will be important to choose the adequate tools of the NLF by identifying those parts of Decision 768/2008 that are relevant for the directive under consideration, in this case the RoHS recast proposal.

The RoHS recast proposal includes a number of provisions of Decision 768/2008, which are actually not of relevance for RoHS. We cite, for example articles 9.4, 15.2, 15.3 or annex VII.7, would not be necessary to be included in the recast RoHS Directive.

V. SCOPE

Orgalime welcomes the proposal to explicitly define the scope of the RoHS Directive directly in the RoHS Directive itself. So far, member states' interpretations on what products would fall under the directive's scope in their country have been somewhat diverging. However, the proposed new annexes I and II remain unclear and should be clarified in the interest of a fully harmonised scope.

When establishing legislation that restricts the use of substances in certain products it is vital that same rules apply for these products throughout all EU member states, since once a product is placed on the market in one member state it is allowed to move freely to all other member states (principle of free movement of goods in the internal market). Diverging requirements in one member state hamper the functioning of the internal market and cause room for free riding, unfair competition and weakened environmental protection.

Orgalime proposal

- Support a fully harmonised RoHS scope
- Establish in first place clear cut criteria in the legal body of the RoHS Directive, which would render product lists redundant, which, due to the vast diversity of different products and speed of change in products can never be complete and up to date.
- If any product list, it must be a binding list to secure a level playing field
- Add a new paragraph in article 3 (a) to clarify the term "dependent" according to the Commission's guidance document (FAQs):

"*Article 3(a): EEE means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields falling under the categories set out in annex 1.A of this Directive.*
Dependent shall mean that the equipment needs electricity as its primary energy to fulfil its basic function."

1. Covered products

Article 2.3 and annex I.6 of the RoHS recast proposal correctly align the scope of the RoHS Directive with Directive 2002/96/EC on WEEE in the area of professional products (business-to-business equipment). We particularly support the proposal to copy the existing exemption of article 2.3 WEEE ("part of another type of equipment") into the RoHS Directive. However, we feel that the clarifications provided by the Commission to this legal provision through its guidance document (FAQ) should be taken up in the legal body of the RoHS Directive, too. This particularly concerns the confirmation that equipment used in finished products outside the scope of RoHS and equipment used in "fixed installations" would be out of the scope. Examples of fixed installations are installations in petrochemical, automobile manufacturing, pharmaceutical, material handling, power generation, water treatment, paper manufacturing plants or certain electrical installations.
"Fixed installation" is a derived term from existing Community legislation, i.e.: article 2(c) of Directive 2004/108/EC on Electromagnetic Compatibility.

The Commission's contracted UNU-EHS WEEE review preparatory study, also confirmed that little could be gained from an inclusion of B2B in the WEEE scope, considering the low environmental relevance of such appliances and the fact that they do not end up in the municipal waste stream. Their end of life treatment is usually addressed in contractual agreements between the affected business partners.

The following further clarifications would be needed to guarantee a level playing field and the application of same scopes in all member states.

Orgalime proposal

- Introduce the missing scope criteria provided in the Commission's FAQ of May 2005 into the legal body of the directive:
  - Article 2.3b shall be completed as follows: "*Equipment which is specifically designed as part of another type of equipment that does not fall in the scope of this Directive, such as part of a finished product outside the scope of the Directive or as part of a fixed installation, and can fulfil its function only if it is part of that equipment."*
  - *The existing definition of "Fixed installations" as provided in article 2.c of Directive 2004/108/EC on Electromagnetic Compatibility shall be introduced in a new article 3(t):* '*fixed installation' shall mean fixed installation in the meaning of article 2(c) of Directive 2004/108/EC on electromagnetic compatibility."*

Orgalime does not in principle oppose 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 (see chapter II of this paper).
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.

Regarding **medical devices**, we support the entry in Annex II declaring that Category 8 (Medical devices) comprises electrical equipment falling within the scope of Directive 93/42/EC. We also support the following definition given in Article 3: "(*m) "medical device" means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EC".*

Regarding **monitoring and control instruments**, we support the following definition given in Article 3(p): "industrial monitoring and control instruments" mean monitoring and control instruments designed for exclusively industrial or professional use. However, it is confusing to find different headings for category 9-equipment in annex I and annex II of the proposal. These headings should be consistent, i.e.: read "monitoring and control instruments".

Orgalime proposal
- Delete the text "*including industrial monitoring and control instruments*" from annex I.9

There is also an overlap between the definition of article 3(p) and the subsequent entry under category 9 in annex II: *"Measuring, weighing or adjusting appliances for household or as laboratory equipment".* Both entries can apply to laboratory equipment used by professionals, but the implementation timescales are different.

Orgalime proposal
- The text "*or as laboratory equipment*" should be deleted such that the entry in annex II then reads: "*Measuring, weighing or adjusting appliances for household use"*

We agree with the recognition that certain category 8 & 9 products are special cases (used in hazardous environments, mission critical functions of reliability, etc.) and as such need additional time to comply with the material restrictions. We therefore support the timescales set out in Article 4(3): "Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 1st January 2014, ……..and to industrial monitoring and control instruments which are placed on the market from 1st January 2017."
The proposed dates are consistent with those proposed by ERA Technology in their report of September 2006.

The effect of including category 8 and 9 equipment within the scope of RoHS too quickly would be that many products would be withdrawn from the EU market, thus disadvantaging European end users who have already made significant investments in systems and personnel that utilise these products. These European users, such as health, research and development, aerospace, industrial manufacturers, power generation, defence, communication, etc. will no longer have access to proven safe and reliable products on the EU market, even though they may still be available to end users outside the EU.

Due to their reliability and cost advantages, many category 9 products are increasingly being used in applications that are specifically excluded from the scope of the RoHS Directive – these include safety applications in military systems, ships, large amusement rides, power generation facilities, chemical and petro-chemical plants etc. Any early inclusion of category 9 in RoHS will therefore inevitably impact safety applications that are outside the scope of RoHS.

Too early inclusion of categories 8 & 9 will also lead to a very large number of very specialised exemption requests, requiring significant time and investment not only from the manufacturer but also the consultant/Commission/TAC.

Furthermore, given the current economic downturn, it is likely that professional users will extend the life of their existing equipment rather than purchase new equipment, and hence funding for redesigns will reduce thus slowing the rate of new product into the market.

It should also be noted that the quantity of category 8 and 9 B2B products placed on the market is negligible compared to other categories – the UK figures for 2008 show:
- Category 8 B2B = 0.63 % of all EEE
- Category 9 B2B = 0.93 % of all EEE

2. Covered substances

Regarding the **necessity of adapting the existing RoHS scope to further substances**, Orgalime expresses its reservation considering both, the still significant problems and uncertainties resulting from the present scope of RoHS and the fact that other Community legislation Regulation 1907/2006 (REACH) in particular, has meanwhile been adopted.

Orgalime believes that a clear policy will become necessary to ensure coherent and consistent requirements for our sector rather than continuing multiplying requirements on same products in different pieces of EU legislation.

In addition, 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 thorough risk assessment a pre-condition for any extension of the present scope of substance restrictions in EEE.
Excluding the Risk Assessment Committee from the future restrictions process would risk conflicting results of the evaluation process and particularly discriminate EEE producers in comparison to producers of other equipment that are assessed under REACH (see section II of this paper).

Orgalime proposal
- Orgalime takes the view that any future assessment, evaluation and restriction of new substances used in EEE shall be established under the REACH Regulation.

VI. EXEMPTIONS MECHANISM, CRITERIA AND RENEWEABILITY

1. The mechanism and criteria for granting exemptions

Orgalime generally supports improving the workability of the existing exemptions mechanism in terms of speed, cost efficiency and more clear and transparent criteria. The existing exemption mechanism has shown to be too lengthy, complex and burdensome a process, which exposes companies to a legal uncertainty and economic risks related to having no alternative available, but fully depending on a, to date, unforeseeable decision making process without any time limits for the Commission to take a final decision.

In practical terms, neither the format of applying for exemptions nor the consultation of stakeholders, nor deadlines for taking decisions have been clear in the past. This should be addressed.

We share the Commission's view that the future exemptions mechanism should include three new criteria, including the socio economic criterion of the REACH Regulation to avoid companies taking advantage of unfair commercial practices (e.g. using IPR to prevent other companies complying with legislation).

Orgalime proposal
- Support the inclusion of the three new criteria in Article 5(1)(b) RoHS
- Introduce a new article 18.a creating a Consultation Forum similar to Directive 2005/32/EC on Eco Design, to ensure a continuous and structured stakeholder consultation mechanism in the implementation process of the directive:

  "The Commission shall ensure that in the conduct of its activities it observes a balanced participation of Member States' representatives and all interested parties concerned, such as industry, including SMEs and craft industry, environmental protection groups and consumer organisations. These parties shall meet in a Consultation Forum. The rules of procedure of the Forum shall be established by the Commission."
- Introduce a new article 5.2a reading as follows: "*The Commission shall adopt its decision on an exemption request as soon as possible, but no lo later than 9 months after the application request for an exemption. The application for an exemption shall be presumed to be granted until the publication of the final Commission decision in the Official Journal of the EU.*"

2. Renewability of exemptions

Orgalime is particularly 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.

This proposed approach will introduce considerable uncertainty, and does not take into account the timescales necessary for product redesign, particularly in the case of categories 8 & 9.

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, instead of the currently proposed maximum validity period of 4 years for all exemptions at once** or practice of expiry of an exemption for procedural reasons alone.

Such a way forward of **reviews on a case by case basis** 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.

Such review periods need to be tackled separately from **transition periods** that would be needed in cases where the review concludes to terminate a certain exemption in its entirety by a given date. Transition periods are necessary to implement substance bans in its global, complex supply chain. They are currently not foreseen in the recast proposal, which should be changed.

A case by case approach on exemptions 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 proposal

- Modify article 5.2 as follows: "*The measures adopted in accordance with point b of paragraph 1 shall determine the review date for the inclusion of any material and application of EEE in annexes V and VI.*"
- Introduce a new article 5.2.b reading as follows: *"In cases where the review justifies terminating a certain exemption, an appropriate transposition period shall apply. Those measures designed to amend non essential elements of this directive, such as details regarding the transposition period, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in article18(2)."*
- Introduce a new article 5.2.c exempting substances used in research and development (so-called PPORD) from substance restrictions in EEE (which is the case under REACH)

3. Annex V on existing exemptions

In the case of the existing exemptions that have already been reviewed during 2008, we understand that the consultant has only partially considered the impact of any changes with regard to categories 8 & 9. A full evaluation will therefore be required, and we propose that the results of the recent study should therefore not be applied to categories 8 and 9. It may be that the new procedure could allow the continued exemption for specific categories say 8 & 9, but be discontinued for other categories, which were fully considered in the consultant's study.

4. Annex VI on exemptions for categories 8 & 9

We support the exemptions listed in Annex VI, which are essential for the continued existence of equipment in categories 8 & 9. However, new types of equipment are under development since this list was compiled (by ERA in 2006) and additional exemptions may need to be added for specialist applications. It is important to consider the almost insignificant contribution (impact assessment) that these two categories of equipment contribute to hazardous substance use compared to other products, particularly those that are mass produced.

VII. GLOBAL COMPETITIVENESS

Orgalime believes that in its international relations the **European Union should foster a common understanding with its key trade partners that have come forward with legislation similar to RoHS,** such as China, including **global harmonisation** of requirements and key compliance aspects (e.g.: definition of homogeneous material).

Considering that more and more countries outside the EU introduce their own national/regional requirements on the restriction of use of hazardous substances in electrical and electronic equipment and considering that our industry acts globally, it is necessary to negotiate a regime such that our industry is presented with a converging legislative approach, leading to a technically, economically and environmentally sound structure in which to manufacture the products that end users require across the globe. While international standardisation is one way to help achieving this, we invite the Commission to better track compatibility of European legislation, such as the RoHS directive, and legislation outside Europe.

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 and the New Legislative Framework in particular. The RoHS recast is an opportunity to do so, especially by clarifying that all criteria and procedural elements of REACH requirements on substance restrictions should apply in their entirety for any future restrictions of substance not covered by RoHS today.

The recast should further more be used as an opportunity to improve the workability of the directive, for example in the areas of scope, exemptions criteria, mechanism and renewability, 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.

ANNEX:

ORGALIME working document comparing the process and criteria of establishing substance restrictions under RoHS and under REACH