Position Paper

Brussels, 27 July 2010

INPUT TO THE REVIEW STUDY OF THE SCOPE OF REACH AND OTHER EU LEGISLATION TO ASSESS OVERLAPS AND GAPS ACCORDING TO ARTICLE 138.6 REACH

Orgalime, the European Engineering Industries Association, speaks for 33 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.6 million people in the EU and in 2009 accounted for some €1,427 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.

Orgalime appreciates the possibility to contribute with its comments to the study on scope of REACH and other relevant EU legislation with a view to assessing possible overlaps and gaps.

The EU's horizontal chemicals law, the REACH Regulation based on article 95, aims at fully harmonising the EU's framework for the management of chemicals, including substance registration, evaluation, restriction and authorisation requirements and uses of substances in the EU.
However, despite the adoption of the REACH Regulation in 2006, several pieces of other EU legislation affecting Orgalime industries continue to include and/or introduce new provisions related to chemical substances, which often create overlaps, legal uncertainty and unnecessary duplication of law, administrative burden and costs. The main consequence of this is that cohesion and consistency are not fully secured for European engineering industries, while at the same time unclear legal requirements also weaken environmental objectives and proper enforcement of law.

In the subsequent chapters, we specify our main concerns on identified overlaps and gaps with four EU other pieces legislation, which directly affect our industries, and we propose recommendations for the way forward.

We hope that the study will take up these areas of overlaps and the necessary background information with a view to addressing them appropriately in any possible Commission proposal for an amendment of Regulation 1907/2006 (REACH) or ongoing legislative procedure, such as on the recast of Directive 2002/95/EC on the Restriction of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS).

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1. Please state whether the issue identified is a gap or an overlap.

☒ Gap (Ecolabel Regulation & IPPC Directive)
☒ Overlap (RoHS Directive, CPD Directive, Ecolabel Regulation & IPPC Directive)

2. Please specify which EU Act it relates to:

A. Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in EEE (RoHS)

B. Directive 89/106 on Construction Products (CPD)

C. Regulation 66/2010 on the EU Ecolabel

D. Directive 1996/61/EC on Integrated Pollution Prevention and Control (IPPC)

3. Please note whether the gap or overlap is related to one or more of the aspects below and describe the gap/overlap in the corresponding column:

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Exemptions	Definitions	Specific Authorisation or Restriction regimes	Substance specific issues	Risk assessment/ risk management issues	Other
A. Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in EEE (RoHS)					
• **Exemptions criteria & procedure** The existing RoHS Directive provides an exemption mechanism and criteria (Article 5). The Annex lists granted exemptions for substance restrictions. These criteria for granting RoHS exemptions are not consistent with the REACH regulation, i.e.: no socio-economic criteria, no criteria of reliability and availability of substances. The exemption procedure of the existing, but also pending proposal for a recast RoHS Directive, overlap with the REACH regulation, since they introduce parallel exemptions to the REACH authorisation procedure. Also future REACH restrictions under Annex XVII		• **Subject matter (Article 1 RoHS & Article 1.1 REACH)** Both, the REACH Regulation and the RoHS Directive, claim to lay down the rules for the restriction of substances for the electric and electronic equipment (Article 1 RoHS & Article 1.1 REACH). Overlapping and conflicts may occur, i.e.: for the use of substances in the context of the manufacturing of electrical and electronic products, between the RoHS requirement and Title VIII REACH on restrictions. Furthermore, overlaps could also occur with title VII REACH on authorisation of the use of certain substances for the manufacturing of electrical and electronic equipment. • **Restrictions (Article 4 RoHS, Title VIII and Annex XVII REACH)** Article 4.1 RoHS restricts the following substance uses: "*Member States shall ensure that, from 1 July 2006, new electrical and*	• **Substance assessment** There is an overlap between the Annex III of the Commission's proposal for a RoHS recast directive and the REACH regulation. The four substances listed for assessment in annex III of the Commission RoHS recast proposal are already included in the REACH candidate list for evaluation. These four substances are likely to be included in the future REACH annex XIV list of substances to be authorised, too.		• **Scope** The scope of the RoHS directive overlaps also with the scope of the REACH Regulation in terms of covered products and covered substances: **a) Covered products** Today, the electrical and electronics industry sector is included in both, the scope of the RoHS Directive

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REACH can be targeted and focus on specific applications. These parallel mechanisms risk introducing conflicting requirements on similar substances in the same products. <u>Proposed solution:</u> All REACH criteria and procedural elements should also apply for RoHS exemptions. • **RoHS exemptions & REACH authorisations** The Commission's proposal for a RoHS recast directive intends to improve consistency and legal certainty in specifying that, for existing RoHS exemptions and finally approved future RoHS exemptions (Article 5.4), no REACH authorisations would have to be sought. However, there still remain some uncertainties and possible risks of overlapping requirements. 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 also count as exemptions from RoHS. Also, during the ongoing recast procedure, proposals for deleting Article 5.4 of the Commission		*electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)*". Title VIII and Annex XVII REACH also restrict the manufacturing, placing on the market and use of certain substances and further substances will be restricted in a near future. These new substance restrictions would also apply to electrical and electronic equipment. • **Methodology for substances evaluation prior to setting restrictions** The REACH regulation restricts the use of substances following a risk based approach, while the existing RoHS Directive follows a hazard based approach. The existing RoHS Directive does not provide any evaluation methodology prior to setting restrictions. However, the RoHS recast aims to introduce an own RoHS methodology in parallel to REACH (article 4.7 of Commission proposal), the details of which remain unclear to date. The development of such a RoHS methodology for substance evaluation in parallel to the existing REACH evaluation procedure and outside the established bodies of the REACH Regulation, such as ECHA and its scientific bodies, will result in a duplication of studies and a multiplication of committees. This again risks conflicting requirements on EEE. <u>Proposed solution:</u> Title VIII REACH methodology should apply also for RoHS. To secure consistency in the EU	Restrictions for these very same substances could also be adopted under REACH soon. During the ongoing RoHS recast procedure, the European Parliament suggests to extend to Commission annex III list from 4 to 36 substances, including all substances listed on the REACH candidate list. This further increases duplication of substance evaluations and possible restrictions. <u>Proposed solution</u>: Any substance assessment should be done in accordance with the REACH assessment methodology, criteria and procedural elements provided for in Title VIII REACH.		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. **b) Covered substances** During the ongoing ROHS recast, the European Parliament proposes to restrict nanosilver and nanotubes in electrical and electronic equipment. In addition,

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proposal are under discussion, which would further increase overlaps in this area. <u>Proposed solution:</u> - Support article 5.4 of the Commission RoHS recast proposal - Introduce a new article 5.5 in the Commission's proposal for a RoHS recast directive, 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*."		chemical management new substances should be assessed with a risk based approach in the light of the EU harmonised framework for chemicals management. Risks related to a substance should be evaluated and assessed from a life cycle perspective, including the end of life phase, according to Article 68-73 REACH. Ongoing discussions on the role of RoHS suggested that RoHS focuses more on the assessment of risks arising during the recovery and disposal phase of waste electrical and electronic equipment. However, these issues can be addressed by the REACH regulation, too: While waste is not a substance, a preparation or an article in the meaning of REACH, REACH evaluates risks related to a substance at the waste stage too. As explicitly mentioned several times in the REACH regulation, the life cycle assessment covers the waste stage of a substance. This is evidenced in several places in the REACH Regulation: • The definition of "exposure scenario" as provided in article 3(37) REACH reads as follows: Exposure scenario means "*the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used <u>during its life cycle</u> and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes*			notification and labelling requirements are proposed for all nanomaterials in EEE. However, nanomaterials are covered by the REACH Regulation (see also Commission Communication on Regulatory aspects of nanomaterials of 2008). <u>Proposed solution:</u> While we agree that nanomaterials should be further investigated and, where deemed necessary, be subject to regulation, we believe that the RoHS Directive is not the appropriate framework to do so, since nanomaterials are used in a wide range of different

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		or uses as appropriate." • This includes considerations related to the waste stage of substances as confirmed in Annex I paragraph 5.2.2 where the life-cycle is explicitly said to cover the waste stage. In addition, Annex I paragraph 5.1.1 of REACH also makes it clear that the Risk Management Measures of an Exposure Scenario should *cover waste management measures to reduce or avoid exposure during waste disposal and/or recycling*. • This information shall consistently be communicated in the supply chain via the safety data sheet, as required in Annex II of REACH. In addition, there are detailed guidance documents of the European Chemicals Agency addressing the issue of waste life cycle stage: • ECHA guidance on information requirements and chemical safety assessments, chapter "R.18: Estimation of exposure from waste life stage" 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, reads that the information on hazard and exposure			applications far beyond the electrical and electronics equipment industry. In case nanomaterials need to be regulated, it should be done within the EU's horizontal chemical management law, the REACH regulation, to avoid double regulation and conflicting requirements.

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		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 <u>Proposed solution:</u> - Any new substances restrictions on electrical and electrical equipment should be fully in line with all criteria and procedural elements provided in REACH Title VIII. - Sectoral legislations, i.e.: the RoHS Directive should use the harmonised methodology with criteria and procedure for preparing substances restrictions provided in Title VIII REACH (Articles 68 to 73). - The added value of the RoHS Directive should be re-evaluated during this REACH recast with a view to integrating the RoHS Directive into the REACH Regulation.			

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B. Directive 89/106 on Construction Products (CPD)					
	• **Definition of "dangerous substances"** While no definition of "dangerous substance" is provided in the legal text of Directive 89/106, the Guidance Paper H ("*A harmonised approach relating to dangerous substances under the construction product directive)* introduces the following definition: "*substances, preparations and radioactive substances that may present a danger for man and the environment during normal use of construction products when installed in works*". Although this Guidance Paper H and other documents, i.e.: the Interpretative Document on Essential Requirement Nr. 3 "*Hygiene, Health and the Environment*" or the mandate M/366 "*Assessment methods relating to dangerous substances"* are not legally binding, they introduce major questions for the implementation of the Directive 89/106, since creating overlaps with the REACH Regulation.		• **Information and communication requirements** When measurement methods will be available, information and communication requirements may be introduced in parallel to REACH via CPD related standards. Some of the current standard mandates include "dangerous substances". Then, manufacturers will have to give this information in Annex Z of the product standard. The overlap is still not clear, since the content of this annex Z in relation to dangerous substances, is not known for the moment being. However, ongoing discussions on the review of Directive 89/106 may introduce a duplication of communication requirements for our industries. In particular, two amendments	The CPD does not introduce itself a risk assessment methodology. However, the previously mentioned Guidance Paper H, that is non-binding, provides a methodology to European standard organisations to deal with dangerous substances (i.e.: identification, verification, selection). The outcome of this methodology is given in document CEN/TC 351 N230rev, which is an indicative list of dangerous substances possibly associated with construction products. Although this indicative list is partially based on Annex XVII REACH, it results in an overlap with the REACH regulation, since it develops its own methodology for substance assessment in parallel to REACH. <u>Proposed solution</u>: - Sectoral legislation, such as the CPD, should use the harmonised methodology provided in Article 57 REACH as well as Article 3 and Annex I of the CLP Regulation 1272/2008 to identify dangerous substances.	

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	Proposed solution: Hazardous substances should in our view be identified on the basis of the criteria provided for in Article 57 REACH.		included in the first reading EP report introduce the obligation to insert information about hazardous substances into the declaration of performance: such information requirements, however, are already covered by Article 33 REACH. In addition, these amendments go far beyond this regulation with regards to the substances to be declared. Proposed solution: - Communication and information requirements should be harmonised at the horizontal level of the REACH regulation instead of being addressed differently in different sectoral laws. - For the review of the Directive 89/106, the institutions should reject the proposed EP amendments 49 and 101 of report of Rapporteur Catherine Neris. - In addition, the implementation of the new recital 21a introduced in the Political Agreement, issued by the Competitiveness Council of 25 May 2010, should be fully in line with Article 33 communication requirements of the REACH	- Furthermore, risks related to the release of substances should be evaluated and assessed with the REACH methodology from a life cycle perspective. - Then, if necessary, any substances with an unacceptable risk to human health or the environment arising at any stage of the life cycle should be restricted in using the harmonised methodology with criteria and procedure provided in Title VIII REACH (Articles 68 to 73).	

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			regulation. - The CPD declaration of performance should not result in additional information and communication requirements.		

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Exemptions	Definitions	Specific Authorisation or Restriction regimes	Substance specific issues	Risk assessment/risk management issues	Other
C. Regulation 66/2010 on the EU Ecolabel					
	• **Definition** The Ecolabel criteria developed for a given product group should be fully coherent and consistent with the REACH regulation. In particular, the identification of substances as specified in article 6.6 of Regulation 66/2010 on general requirements for Ecolabel criteria may result in overlaps REACH. Article 6.6 states that "*The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation*			• **Derogations from Article 6.6** We support the fact that substance requirements for the award of the EU Ecolabel adhere to REACH requirements when setting Ecolabel criteria for product groups. While we agree that criteria can be more proactive in nature where this is scientifically justified and technically possible, the award criteria should respect REACH requirements. Article 6.7 of the Eco label regulation, which grants derogations from article 6.6 of Regulation 66/2010, reads as follows: "*For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6. No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight). Those measures, designed to amend non-essential*	

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	and Restriction of Chemicals (REACH), establishing a European Chemicals Agency". The Eco Label Regulation itself does not provide definitions for *toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR).* The wording of article 6.6 also means that there is no automatic restriction of the use of such substances in all eco-labelled products. The risk linked to substances should be identified according to the risk in using a substance in a specific product. Any substance should not be automatically phased out from the Ecolabel award scheme since even where such a substance fulfils Article 57 REACH criteria, the risk depends on its specific use. Otherwise, it would result in separating the substance management from the life cycle approach of REACH. Just as for the REACH regulation, the emphasis should be put on the risk and how it can be handled, i.e.: during the waste management phase. <u>Proposed solutions</u>: - The definitions provided for in the REACH Regulation and CLP Regulation should apply for the implementation of the Eco Label Regulation. - For the implementation of Regulation			*elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(2).*" The above mentioned article 6.7 of Regulation 66/2010 creates a gap between the Eco-label award scheme and the REACH Regulation. No derogations from article 6.6 of Regulation 66/2010 shall be granted for substances included in the REACH Candidate list. However, alternatives are not available in all cases. Availability of alternative, as well as their impact socio-economic and environmental impact, should also be considered. Any substance ban, even in the context of an award scheme, should have a scientific basis and be fully in line with all criteria and procedures provided in REACH. <u>Proposed solutions</u>: Fill the gap of article 6.7 of regulation 66/2010 by clarifying that derogations should also be possible for substances included in the REACH Candidate list.	

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	66/2010, a case by case approach should be taken for deciding whether a substance may be used in a given eco labelled product group according to its risk. - For that purpose, all REACH findings and the knowledge obtained from its implementation, such as risk assessments and studies, should be used for the implementation of the Eco Label Regulation. - In the context of the REACH review, a reference should be included in the REACH Regulation that REACH findings and the knowledge obtained from its implementation, especially risk assessments, studies etc, are applicable to other EU legislation, such as Regulation 66/2010, and their implementation.				

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D. Directive 1996/61/EC on IPPC (as codified in Directive 2008/1/EC)					
		• **Annex III: Emission Limit Values** Annex III of the IPPC Directive 1996/61 (that is the Annex II of the Commission's proposal for an IPPC recast directive) lists relevant substances for which emission limit values should be fixed. However, most of these substances are already identified as dangerous substances and/or included in the REACH Candidate list. Proposed solutions: To avoid possible of overlap and unnecessary multiplication assessments of substances, all REACH findings, i.e.: risk assessment, studies, exposure scenarios, etc., should be used as a main source of information and taken into account for the establishment of emission limit values under the IPPC Directive. • **Environmental impact assessment** As stated in the article 10 IPPC Directive 1996/61, permitting is based on an environmental risk assessment. However, exposure scenarios must be included in the registration dossier of any substance manufactured at 10 tonnes or more per	• **EPTR (Regulation 166/2006)** Regulation 166/2006 establishing a European Pollutant Release and Transfer Register, introduces some communication requirements in amending the IPPC Directive 1996/61. Release of specific substances to air, water and land, in the context of activities listed in Regulation 166/2006, exceeding certain thresholds must be reported. However, some substances, for which a report is needed, are considered as dangerous or fulfill PBT and vPvB criteria. Overlaps with the REACH Regulation may occur since exposure scenarios are required for these substances.	• **Implementation: BREFs (Article 17 & Annex IV)** In Directive 1996/61 on IPPC as well as in the ongoing discussion on the review of this Directive, Reference documents on Best Available Techniques, so-called BREFs, are used to minimise risks for the environment. However, somehow BAT seem to overlap with risk reduction measures in REACH and has not been coordinated with REACH. Proposed solutions: To avoid such overlaps, BREFs and risk management measures should be aligned.	• **Environmental risk assessment** A gap could be identified between the REACH regulation and the IPPC directive regarding the environmental risk assessment related to the use of substances. REACH does not require suppliers of chemicals to provide the exposure scenario if they produce less than 10 tonnes per year. Proposed solutions: Regardless of tonnage of that substances used, installations covered by IPPC should have the right to receive further information on environmental risk

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		year and considered as dangerous according to Regulation 1272/2008 as well as PBT and vPvB substances. According to article 3.37 REACH, the exposure scenario describes the conditions according to which the risks to human health and the environment are adequately controlled. It describes how the substance is manufactured or used during its life-cycle. Proposed solutions: To avoid duplication of assessments, the exposure scenario should replace parts of the IPPC assessment, since necessary information has to be provided under the REACH Regulation. To identify best available techniques, Annex IV. 2 of the IPPC Directive advises to substitute hazardous substances. However, the substitution of hazardous substance is already handled in REACH through the authorisation / restriction process.	Proposed solutions: To avoid overlaps in terms of communication requirements on substances, emission of substances in line with the exposure scenarios should not require reporting.		assessment of substances, even if exposure scenarios are not mandatory. • **Review** The IPPC Directive is currently under review. Further inputs may therefore be provided later this year, on possible overlaps and gaps with the recast IPPC directive, now called Industrial Emissions Directive.

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