Orgalime comments on the interpretation of article 7.2 REACH

Brussels, 7 February 2007

***Orgalime**, the **European Engineering Industries Association,** speaks for 36 trade federation representing some 130,000 companies in the mechanical, electrical, electronic and metalworking industries of 24 European countries. The industry in 2005 accounted for some €1,598 billion of annual output. The industry does not only represent more than one quarter of the output of manufactured products but also a third of the manufactured exports of the European Union. It is the largest manufacturing sector in Europe. It is also the largest industrial employer in the EU27, providing some 10 million jobs.*
***In terms of REACH**, Orgalime does not only represent a **major downstream user**, but with annual imports of some 30 billion components for manufacturing activities in Europe, Orgalime represents the **major industry branch that will be required to implement article 7 REACH**. The industry is characterized by **highly complex global supply chains** that operate under highly competitive conditions with **"just in time"** flows of most components. We are the **supplier of technology to all other industry sectors**, including automotive, aerospace or chemical industries.*

Orgalime understands that the Commission Working Group on the Practical Preparations for REACH (CWG) has launched a CWG subgroup in order to discuss fundamental issue of how to interpret certain requirements on substances in articles in the context of RIP 3.8.

We understand that the subgroup will examine **the legal interpretation of article 7.2 REACH, i.e.: the calculation of the presence of the substance in the article in a concentration superior to 0.1% weight by weight.**

Orgalime fully supports the approach taken in the final report of RIP 3.8 of 26 May 2006, which clarifies that **"*the concentration threshold of 0.1% (w/w) refers to the average concentration of the article as produced or imported*[1]"**. We urge regulators to stick with this understanding for the following reasons:

- The content of any REACH guidance document, including RIP 3.8, in our view cannot introduce stricter requirements than those given in the legal body of the REACH regulation. In particular, article 7.2 REACH refers to the article itself and does not mention "homogenous material". On the contrary, during the legislative process, an amendment on "homogeneous material" was not taken up in the finally agreed text. We believe therefore that any guidance document cannot go beyond the given legal requirement. Such an interpretation would without doubt be challenged in European Courts.

- There is no proven, well working, harmonised definition of what constitutes a "homogeneous material", neither across Europe, nor globally. Notwithstanding that a number of substance use restrictions, such as established by directive 2002/95/EC on RoHS or directive 2000/53/EC on end of life vehicles, are supposed to apply at the level of homogeneous material, experience shows that the "homogeneous material" definition is open to different interpretations, resulting in weakened enforceability. Also, in so far as they exist, the definition and application of "homogeneous material" is different in these directives: While for the EOLV directive the definition includes the

[1] Draft Technical Guidance document on requirements for substances in articles. Reach Implementation project 3.8 Final Report, 26 May 2006, p. 32.

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criteria of “(un)intentional release”, the definition for the RoHS directive does not refer to this criterion.

- Under these directives, the application of “homogeneous material” has shown clear limits, e.g.: An exemption to the RoHS directive has been requested for hexavalent chromium passivation coatings since there is no practical means of determining the quantity of hexavalent chromium within the homogeneous material coating layer. The automotive industry has moreover been granted an exemption for hexavalent passivation coatings particularly for fastener and bolts under the EOLV directive. We are seriously concerned that, given the much broader scope of REACH, the issues we are encountering with RoHS will again arise but on much greater scale when implementing REACH, thereby hampering the competitiveness of our industry.

- Calculating concentration values at the level of the homogeneous material of an article would furthermore exponentially increase the number of required notifications at the Chemicals agency. While we challenge the capacity of the agency to react properly and timely on given notifications, we are concerned about the fact that our industry would be required to carry out time-consuming administrative tasks without proven benefit to the environment or human health.

- We are also concerned that skilled personnel would have to concentrate on sorting out paper work and administrative tasks, instead of investing time and resources into the development of new innovative products. This runs counter Better Regulation principles.

- Finally, we believe that consistency and coherence of product related legislation, and those addressing substance aspects in particular, are a prerogative for preserving the functioning of the internal market and free movement of goods therein. As far as Orgalime industries are concerned, particular sector specific legislation already exist, i.e.: Directive 2002/95/EC on the restriction of the use of certain substances in electrical and electronic goods or directive 2005/32/EC on eco design requirements that includes substance aspects over the life cycle of energy using products. We object that through erroneous application of REACH additional inconsistent requirements are established on engineering products, which would cause further uncertainty and unenforceability.