ORGALIME

# Position Paper

**Brussels, 03 August 2012**

# Orgalime comments on the reports of the Internal Market and Consumer Affairs Committee of the European Parliament on the alignment of 9 directives with Decision 768/2008

*This position paper comes as a follow-up to the Orgalime position (04/06/2012) on the reports of Ms Roithová, Rapporteur, on the alignment of 9 Directives with the New Legislative Framework in view of the further discussions in the working group of the Council.*

## 1. GENERAL IMPROVEMENT OF THE EUROPEAN COMMISSION PROPOSALS

Orgalime welcomes the reports of Ms Roithová on the alignment of 9 directives with the New Legislative Framework. We appreciate the efforts of the Rapporteur and the members of the Internal Market and Consumer Affairs Committee (IMCO) of the European Parliament to resist the incorporation of too many suggestions for changes which would clearly deviate from a pure alignment (e.g. a reform of the accreditation system). We also welcome the reaffirmation of the principle of **non-retroactivity** of the law in several provisions, as this will enhance the legal certainty for all economic operators.

Furthermore, several amendments that the IMCO Committee introduced will probably contribute to a flexible and yet more effective market surveillance system. In particular, Orgalime appreciates the possibility given to manufacturers to indicate their **website address** instead of their postal address on the product, as well as the possibility to indicate contact information either **on the packaging or in an accompanying document**, where it is not reasonably possible to place it on the product. We welcome the introduction of the possibility for manufacturers to provide upon request by the national authorities the **Declaration of Conformity (DoC) in electronic form**, and its **unique identification numbering** as per EN 17050-1, instead of an identification numbering of the product, because this is already addressed explicitly under point 4 of the model DoC. Thus, the DoC could apply to variations of the same product (e.g. same model, slightly different functionality or colours).

Moreover, Orgalime is particularly pleased about several provisions which ensure a full alignment while preserving the integrity of the technical content of the directives, including:

- The (re)introduction of the **possibility to use accredited in-house bodies** in SPVD and ATEX directives, as the Orgalime members have a positive experience from the use of such bodies. It should be stressed that the competence and independence of these bodies is ensured, as for any other accredited conformity assessment body, by the system of



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European accreditation which is operational under Regulation EC 765/2008 since 2010 (European Commission Proposal for ATEX: Annex VI – point 3 – paragraph 1, European Commission proposal for SPVD: Annex II – part 2 – point 2.3 – point 2.3.1 – introductory part, Annex II – part 3 – point 3.3 – paragraph 1)

- The removal of the obligation to provide a colour image to accompany the declaration of conformity in Annex IV of the LVD proposal, as such a requirement does not exist in Annex III of Decision 768/2008.
- The re-establishment of the current definition of electromagnetic disturbance in Article 3 – paragraph 1 – point 5 of the European Commission's proposal for the EMC, as this has served its purpose well for several years.
- The re-introduction of the manufacturer's choice for one of the 2 conformity assessment procedures in the EMC proposal (Article 7 paragraph 2 and Article 14 of the European Commission Proposal for the EMC)
- The deletion of the provisions in article 7 of the European Commission's proposal for the EMC, which refer to "*putting an apparatus into service*", as these would only create confusion on the different roles of economic operators.
- The deletion of indent 5 of Annex III – point 3 – paragraph 1 of the European Commission proposal for ATEX, as this removes an editorial mistake in the proposal that could create confusion.

## 2. AMENDMENTS THAT MAY CAUSE LEGAL UNCERTAINTY

Orgalime recognises the EP IMCO's choice to strengthen the protection of end-users against non-conforming and dangerous products. However, we consider that changes to the original provisions on conditions for making products available on the market are opening up to varying interpretations and thus contribute to legal uncertainty for lawful manufacturers.

In particular, Orgalime regrets the insertion of wording which invites authorities to assess the making available of a product on the market against requirements for "***applications which can be reasonably foreseen***". Such a formulation does not appear in Decision 768/2008 or in any piece of legislation which is likely to be aligned with the New Legislative Framework and deviates from a pure alignment. It suggests that the product should not cause harm even when used for applications that are either forbidden by the manufacturer in the user instructions or the safety warnings or are completely irrelevant to the intended use of the product.

The similar concept of "***reasonably foreseeable conditions of use***" is not included in the provisions on manufacturers' obligations in Decision 768/2008 either, and thus should not be introduced in the text of the Directives. Experience shows that the application of such a concept under the GPSD and some new approach directives has been subject to scattered and diverging interpretations by Member States, thereby raising new barriers to trade within the Internal Market. Therefore, Orgalime calls on the Council and the Parliament to come back to the original wording the Recast proposals (LVD: Article 3 – paragraph 11; EMC: Article 4 – paragraph 1; ATEX: Article 3 – paragraph 1; SPVD: Article 3 – paragraph 1).

Finally, Orgalime regrets that the EP IMCO added **the exception of products used in research and development** on a business to business basis from the scope of the LVD and EMC Directive. These directives are set to ensure the health and safety of all users of products under their scope, including products intended for use by researchers in laboratories. Orgalime is also concerned that this exception may cause confusion, as market surveillance authorities are not always in position to evaluate if a product will be solely used for R&D purposes or not, especially if they conduct controls at the borders or other places of massive storage. (LVD: Annex II – paragraph 8 a (new); EMC: Article 2 – paragraph 2 – subparagraph 1 – point c a (new))

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