

Brussels, 4 June 2012

Orgalime Comments on the draft report of Ms Roithová on the alignment of 9 Directives with Decision 768/2008 – NLF or “Goods Package”

European Parliament Draft Reports of the Internal Market and Consumer Affairs Committee
2011/0351(COD)

1. GENERAL COMMENTS

Orgalime welcomes the Draft Reports prepared by Ms Roithová, the Rapporteur of the Internal Market and Consumer Affairs Committee of the European Parliament. These reports mirror most of our concerns about inconsistencies in the Commission’s recast proposal.

We especially welcome the Rapporteur’s suggestions to:

- further align the 9 directives with the NLF (including a reference to in-house accredited bodies) and ensure legal certainty (reference to the principle of non-retroactivity of the law);
- reduce the red tape on issuing the declaration of conformity (possibility of an electronic format);
- insist on ensuring better market surveillance for products placed on the internal market.

As to the Rapporteur’s ambition to enhance consumer protection, we firmly believe that this will result from an effective and efficient enforcement of the 9 directives. For example, the Low Voltage Directive (“LVD” - [2006/95/EC](#)) exactly as the other directives has proved to work satisfactorily as regards ensuring a high level of safety for products lawfully placed on the Internal Market, including for so-called “*vulnerable consumers*”: children, the elderly and persons with disabilities. Therefore in our view there is no need for amendments to the technical content of this or other directives under the package. We strongly support a “pure” alignment of the directives with the New Legislative Framework (NLF).

As a consequence, we are wary of the changes suggested by the Rapporteur to the technical content of some directives, especially the LVD. In our view, these changes exceed the recast exercise and are out of the scope of the impact assessment conducted by the European Commission. The proposed changes would cause a serious problem for manufacturers and standardisers for the following reasons:

Orgalime, the European Engineering Industries Association, speaks for 34 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

- For many years our industry has invested considerable resources in drafting the many hundreds of standards that support these directives.
- In addition to being adopted as "EN" standards, many of these standards have also been accepted as IEC standards, thereby reinforcing the competitive position of the EU's electro-technical industry on world markets.
- Therefore changes to the technical Annex would not only lead to additional administrative procedures for manufacturers in order to adapt to these requirements, but will also result in the setting up of a new standardisation programme at huge cost for industry and other stakeholders, that may be out of proportion to the expected benefits, especially for SMEs.
- This will also have unforeseeable consequences on international standardisation and on our industry's capacity to export internationally, which is particularly important, as the industry we represent is one of the main sources of growth and employment in manufacturing industry.

2. DETAILED COMMENTS ON HORIZONTAL POINTS

2.1. Further align the directives with the NLF and ensure legal certainty

Orgalime welcomes the introduction of the option for the manufacturer to make use of **an accredited in-house body** for the modules A1, A2, C1 or C2 which was foreseen in Decision 768/2008. This has so far proved to be very efficient and cost-effective, especially for consortia of SMEs (e.g. in the North of Italy), for providing checks according to the legal requirements, compared to the costs of third party certification services. (ATEX: Amendment 27; SPVD: 30, 33; Pyrotechnics: 48; Civil explosives: 31; MID: 24, 25; **NAWI: missing Amendment in Annex II**).

We also appreciate the amendments of an editorial nature that bring the recast proposals closer to the wording and structure of Decision 768/2008 (e.g. ATEX: Amendments 4, 14, 16, 21 and 26; EMC: 4, 5, 22; LVD: 6, 7; 8, 9; MID: 3, 4, 5, 6, 19; SPVD: 5, 25).

2.2. Enhance Consumer Protection

Orgalime opposes the inclusion of provisions referring to the concept of "**vulnerable consumers**", which is a source of open and diverging interpretation. For manufacturers, the same level of protection should apply to all those for whom the product is designed. It is important that manufacturers are not held liable if, in the future, a material or process is found to be hazardous. For the Lifts Directive in particular, such an amendment is inappropriate as the Directive refers solely to components to be placed on the market and installed by trained professionals and not by consumers. Facilitated access in public buildings for persons with disabilities is dealt with in other legislation (LIFTS: Amendment 1, 4, 8; LVD: 1, 5, 11; NAWI: 8, 9; Pyrotechnics: 1, 3).

Orgalime does not support the amendment appearing in several Directives that asks for a product to be "**accompanied by instructions and safety information**", because instructions that are relevant to safety are included in the wording "safety information" which appears in the European Commission proposal. Quality instructions or any other instructions do not need to accompany the product and introducing such an obligation would deviate from a strict alignment and add unnecessary costs to economic operators. Additionally, we consider that the amendment stating that "*such instructions and safety information as well as any labelling shall be clear, understandable and intelligible*" is too vague. It could be misinterpreted by market surveillance authorities and result in further red-tape for lawful manufacturers (ATEX: Amendment 6; EMC: 8; LVD: 15; MID: 7; SPVD: 12).

Finally, **Orgalime is firmly against the inclusion** of a provision regarding a product "*used in applications for which it was made or in applications which can be reasonably foreseen*". This

deviates from Decision 768/2008 and carries the risk of varying interpretation from one Member State to another. Most importantly, this provision was not taken into consideration in the drafting of most existing standards, as it was not part of the legislation. This would therefore lead to having to revise a large number of standards with a huge economic impact. Orgalime proposes instead to use the lead concept in New Approach legislation of “*intended use*”, which better defines the extent of the obligations of manufacturers and is well known by market surveillance authorities (ATEX: Amendment 5; Civil explosives: 29 & 30; EMC: 6; LVD: 10 & 14; Lifts: 6 & 7; MID: 8; NAWI: 26 & 27; Pyrotechnics: 35; SPVD: 7).

2.3. Cut Down Red Tape

Orgalime appreciates the sincere effort of the Rapporteur to introduce amendments that would reduce the red tape faced by economic operators. With this in mind, we would like to suggest alternative wording which, in our opinion, could achieve this goal in a more effective manner.

- We call on the European Parliament to adopt the following wording for the amendment that facilitates the manufacturer’s duty to draw up a single Declaration of Conformity for all the legislation that a product has to comply with:

When ~~if~~ issuing a single EU declaration of conformity ~~could cause~~ specific problems due to the complexity or scope of that single EU declaration, it should be possible to replace that single EU declaration by individual EU declarations of conformity relevant for the particular product.

- Orgalime firmly supports the possibility for manufacturers to present the Declaration of Conformity in **electronic form** as it increases the number of ways to comply with the market surveillance and traceability requirements and facilitates the work of market surveillance authorities in their dialogue with economic operators (ATEX: Amendment 12; EMC: 16; LVD: 24; MID: 13 SPVD: 18).
- Orgalime welcomes the explicit confirmation of the **principle of the non-retroactivity of legislation** regarding the transition between existing and new Directives (EMC: 12; LVD: 19; MID: 9; ATEX: 7; SPVD: 14). In line with the principle of non-retroactivity of legislation, whenever product checks are made along the distribution chain, compliance is verified also against the versions of harmonised standards that were valid when the product was placed on the market, irrespective of any later changes in these harmonised standards. Therefore, Orgalime proposes to the European Parliament to introduce the more general wording used in the ATEX proposal (amendment 1) in the body of the 9 Directives:

Member States should ensure that products which have been placed on the market in compliance with the requirements applicable at that time can continue to be made available by distributors without further requirements.

Finally, Orgalime regards as positive the amendment introduced in the EMC Directive which asks for a **unique identification number of the Declaration of Conformity** (DoC) itself as per EN 17050-1, instead of the product, because the DoC could apply to variations of the same product (e.g. same model, slightly different functionalities or colours). We thus suggest to the European Parliament to introduce the same amendment in all the 8 other Directives. (EMC: Amendment 27)

2.4. Ensure a better market surveillance for our products

Orgalime welcomes the Rapporteur’s emphasis on ensuring a higher level of market surveillance of products. However we believe that the forthcoming new regulation on market surveillance prepared by the Commission’s services will more adequately provide a common approach to the market surveillance of all products, including those falling under the scope of these 9 directives, whether distributed via distance selling or not.

3. DETAILED COMMENTS ON SPECIFIC DIRECTIVES

3.1. Low Voltage Directive 2006/95

Orgalime welcomes the amendment to Annex IV of the European Commission proposal which states that the DoC **may include an image**. This amendment improves the European Commission proposal which requests that the DoC “*shall include a colour image of sufficient clarity to enable the identification of the electric equipment*”. However, Orgalime would prefer the exact wording of Decision 768/2008, which is “**may include a photograph, where appropriate**”. Orgalime considers that reinstating the provision of the existing Directive is the only way to consistently apply the NLF and to avoid unnecessary bureaucratic burden:

- While the provision of a colour image may be relevant for some consumer products, such a requirement is irrelevant for most industrial products falling within the scope of the LVD. For these products, the differences between various models simply cannot be identified from a comparison of 2 photographs/images. For example, 2 different power supply units from the same manufacturer or even from 2 different manufacturers could not be distinguished by a picture as they are all black and box-shaped.
- Identification requires checking the name of the manufacturer and the model and series numbers under which the product was placed on the market. This information is available in the DoC.
- The provision of a colour image would add administrative burden and disproportionate additional costs (conversion of processes to costly colour printing) for manufacturers, especially for professional LVD products. This would be further aggravated if the requirement for a single DoC were maintained (see Chapter 1 point 2 above) in all those cases where the DoC is required to accompany the product (e.g. for all machinery).

3.2. Electromagnetic Compatibility Directive (2004/108/EC)

Orgalime appreciates amendments 7, 9, 10 and 11 which delete the words “**and/or putting them into service**”, and amendment 28 which deletes the words “**(or installer)**” as they remove the risk of confusion about the responsibilities of manufacturers. The EMC Directive includes both apparatus and fixed installations, but specifies separate provisions for each. Due to their specific characteristics, fixed installations are not subject to an EU DoC and are not subject to CE marking.

However, Orgalime regrets that its proposal to leave **the choice of the conformity assessment procedure up to the manufacturer** was not taken on board. In the current EMC Directive, the choice of the conformity assessment procedure that is described in Article 7 is at the sole discretion of the manufacturer: “*However, at the discretion of the manufacturer or of his authorised representative in the Community, the procedure described in Annex III may also be followed*”. This provision has been deleted without reason from the text of the recast Directive. Therefore, Orgalime calls on the European Parliament and the Council to reintroduce this clarification into the text of the recast proposal in the following two Articles:

- **Article 7 paragraph 2** of the recast proposal on the obligations of manufacturers: “the technical documentation referred to in Annex II and/or Annex III **respectively**”.
- **Article 14**: “**At the discretion of the manufacturer**, compliance of apparatus with the essential requirements set out in Annex I shall be demonstrated by means of either of the following procedures.”

--- + - + - + ---

Advisers in charge: Philippe Portalier (name . lastname @ Orgalime . org) &
Efthymia Ntivi (name . lastname @ Orgalime . org)

The European Engineering Industries Association