ORGALIME

Position Paper

Brussels, 5 March 2012

Alignment Package of 9 product harmonisation Directives with Decision 768/2008/EC - NLF or 'Goods package'

European Commission proposals for the alignment of the existing legislation with the provisions of Decision 768/2008 (NLF Alignment Package)
(2011/0349 (COD) -2011/0350 (COD) - 2011/0351 (COD) – 2011/0352 (COD) - 2011/0353 (COD) - 2011/0354 (COD) - 2011/0356 (COD) - 2011/0357 (COD) - 2011/0358 (COD))

Orgalime welcomes the New Legislative Framework and therefore supports the Commission Proposal to align 9 product harmonisation Directives as closely as possible with the New Legislative Framework (Regulation (EC) 765/2008 and Decision 768/2008/EC). The Directives should be aligned with the NLF in a consistent way in order to avoid any unjustified discrepancies. As already stated during the discussions on the 2008 Marketing of Goods Package, we believe that EU legislation should be simpler in order to be easier and less costly to comply with, easier to enforce and more efficient to support investments, growth and jobs in Europe. This is even more true in these challenging times for European manufacturing. The consistent application of the NLF will be a practical step towards helping to reach this goal.

Therefore, we greatly appreciate the fact that the European Commission has almost entirely followed this path. With this in mind, we urged the Commission to clarify in a revision of the Blue Guide or in separate guidance documents a number of elements contained in the reference provisions set out in Decision 768/2008/EC (cf Orgalime position of 11 October 2010) rather than introduce changes to the NLF provisions in the revised Directives.

However, there are 2 points on which we see the need to consider a consistent clarification across the 9 recast directives and that we explain below under general comments. Furthermore, we provide a few specific comments on selected recast proposals.

1. General comments

1) Clarification is needed as to the distributors' obligation of due diligence[1], which should refer to the requirements applicable *at the time of the first making available* (= placing on the market) of the products in stock.

[1] *Article R5 (1) of Decision 768/2008/EC: "When making a product available on the market distributors shall act with due care in relation to the requirements applicable."*

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 9.7 million people in the EU and in 2010 accounted for some €1,510 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.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

EU legislation generally follows the principle of non-retroactivity of law: a product that has been lawfully placed on the market in conformity with the provisions of the legislation applicable at the time, is allowed in principle to continue to circulate freely within the internal market even after legislation changes.

- However, in the 9 recast Directives, the articles that are aligned with paragraphs R5.2.2 and R5.4 of Decision 768/2008/EC require distributors who consider or have reason to believe that a product, which they are about to make or have already made available on the market, is not in conformity with the applicable Directive to take necessary corrective measures. It is not clear at which point in time this obligation of due diligence should apply and to what extent it should take into consideration the date of the first placing of the product on the market by the manufacturer or the importer.
- The current wording leaves room for misunderstanding and creates legal uncertainty as to whether the principle of non-retroactivity of law is adhered to or not. Distributors risk having products in stock that they cannot make available to the final customer whenever the provisions of applicable legislation change.
- For instance, the current Low Voltage Directive 2006/95/EC does not require the affixing of the manufacturer's address on the product. Will distributors be required to take action for their products in stock when the recast of the LVD enters into force?

If the principle of non-retroactivity of law were not adhered to, many products in stock within the distribution chain would no longer be in conformity, although they were lawfully placed on the market. Therefore, **Orgalime calls for clarification in the recitals of** each of **the 9 recast Proposals**, or even for the inclusion of an additional provision e.g. under the recast articles aligned with Article R5 (obligations of distributors) of Decision 768/2008/EC:

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

2) The drawing up of a "single" EC declaration of conformity should remain optional and not become a requirement.

*In line with Article 5 of Decision 768/2008/EC, the recast proposals provide that "a **single** declaration shall be drawn up in respect of all Union acts applicable to the product containing all information required for the identification for Union harmonisation legislation to which the declaration relates, and giving the publication references of the acts concerned".*

Orgalime suggests maintaining the status quo and leaving it to the discretion of the manufacturer to opt for one or several declarations of conformity (DoC). This could be done horizontally by adding the formula "where suitable" (or similar) in the corresponding paragraphs of the 9 recast directives. Such flexibility is needed for the following reasons:

- Currently, depending on the product and the internal processes, the manufacturer chooses whether to mention all relevant directives and related harmonised standards in a single DoC or to have separate DoCs for each directive. Since some complex products are within the scope of a relatively large number of directives, for example LVD, EMC, ErP and RoHS, mentioning all these directives and the related harmonised standards in a single DoC can result in a relatively complex document. The manufacturer will have difficulty compiling this document and keeping it up-to-date, and Market Surveillance Authorities will find it difficult to read.
- There is no clear added value of a single DoC for Market Surveillance Authorities, as in most Member States different authorities are responsible for the market surveillance of different Directives. Market Surveillance Authorities therefore only require information related to the scope of the Directive(s) for which they are responsible.
- Some Directives (e.g. the Machinery Directive) that could apply in addition to one of the 9 Directives to the very same product require that the DoC accompanies the product. For products in series, these DoCs are printed in large numbers and packed with each product in

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 414341438

stock. If the requirement for a single DoC were to be maintained, it could create significant update problems for products that are covered by several Directives. For instance, a change to a harmonised standard, which is referenced in the DoC, would mean adapting the DoC accordingly. Hence, instead of adapting the relevant parts only, the requirement for a single DoC would significantly increase the frequency of changes to the whole document. This would imply additional document management burdens and re-printing costs for manufacturers without any clear added value for the enforcement authority.

2. Specific comments related to the recasts of selected Directives:

a. Electrical equipment designed for use within certain voltage limits (LV D) Recast. 'Goods package' - 2011/0357(COD)

- **The requirements for the EU Declaration of Conformity** (DoC - Annex IV of the proposal) **should be fully consistent with** the relevant NLF reference provision, i.e. Annex III to Decision 768/2008/EC.
    - While Annex III to Decision 768/2008 clearly stipulates that the DoC "***may include*** *a photograph, where appropriate*", this text was changed and turned into a formal requirement by the recast proposal which provides that the DoC "***shall* include a colour image of sufficient clarity to enable the identification of the electric equipment**".
    - Orgalime urges the European Parliament and the Council to reinstate the provision of the existing Directive and to consistently apply the NLF reference provision, which leaves it up to the manufacturer to decide whether the inclusion of a (colour) photograph is appropriate, for the following reasons:
        - 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 between 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).

b. Electromagnetic compatibility (EMCD). Recast. 'Goods package' - 2011/0351(COD)

- **The choice of the conformity assessment procedure should remain with the manufacturer.**
  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

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
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European Parliament and the Council to reintroduce this clarification into the text of the recast proposal in the 2 following 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."

- **Confusion should be avoided on who is to issue the declaration of conformity**

  The EMCD recast proposal states in Annex IV "*Technical documentation and EU declaration of conformity*" under point 3 that "*This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer*)".

  We suggest deleting the words "(or installer)" as this may lead to confusion in the context of the EMC Directive.

  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 declaration of conformity and are not subject to the CE marking.

c. Equipment and protective systems intended for use in potentially explosive atmospheres (ATEX). Recast. 'Goods package' - 2011/0356(COD)

- **Inconsistency of the definition of "component" and "equipment" with the general meaning of "products" in Article 1.**
  - **Article 2** ⌦ Definitions ⌫ – The definition of **component** in the existing directive has not been updated in accordance with the meaning of the aligned Article 1 of the recast. As this could lead to legal uncertainty, Orgalime suggests changing the word "component" into "**product**".
  - Similarly, **Annex I** on "*criteria determining the classification of **equipment**-groups into categories*" should read "criteria determining the classification of **product**-groups into categories".
  - Similarly, **Annex II** on "*essential health and safety requirements relating to the design and construction of **equipment** and protective systems intended for use in potentially explosive atmospheres*" should read "essential health and safety requirements relating to the design and construction of **products** and protective systems intended for use in potentially explosive atmospheres".

- **Absence of an obligation to carry out sample testing of marketed products**
  - We **welcome** the decision of the Commission to refrain from introducing into the recast proposal obligations for economic operators to carry out sample testing of marketed products (Articles R2 (4) and R4 (6) of Decision 768/2008/EC).
  - These obligations were taken from the General Product Safety Directive 2006/95/EC, which applies to consumer products. The ATEX Directive 94/9/EC covers professional products that are not intended for use by consumers and provides for a specific marking to demonstrate that the product is intended for use in explosive atmospheres. Moreover, the introduction of such a provision would also conflict with the private contractual arrangements between the manufacturer and his professional customers.

- **Difference in the order of markings as stipulated in the current Directive and in the EC recast proposal**

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
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- In Article 16 [Article R12 of Decision No 768/2008/EC] on "Rules and conditions for affixing the CE marking and the specific marking of explosion protection", the provision changes the marking requirements of the current ATEX directive. In the current directive, CE marking is followed by the identification number of the Notified Body and further markings such as that of explosion protection  . In the proposed text of the recast, the marking of explosion protection is required first and the NB identification number at the end. Such a change, which appears to be editorial, could induce significant costs to companies in order to update their conformity assessment and marking procedures, without any clear added value. Orgalime urges that the status quo should be maintained .

- **Language requirement of the documents for notified bodies**
  - Article 13 of the ATEX Directive addresses conformity assessment procedures, which are of no concern to the end-user of the product. There is no particular obligation related to the language in Article R17 of Decision 768/2008/EC on requirements relating to notified bodies. However, the text was changed as follows in the recast proposal:

    Article 13
    (…)
    6. Documents and correspondence relating to the procedures referred to in ~~the abovementioned~~ paragraphs ⌦ 1 to 4 ⌫ shall be drawn up in ~~one of the official languages of the Member States in which those procedures are being applied or in a language accepted by the notified body~~ ⌦ a language easily understood by end-users, as determined by the Member State concerned ⌫ .
  - We believe it is a mistake to have adapted Article 13 paragraph 6 to Article R2 paragraph 7 of Decision 768/2008/EC (obligations of manufacturers). Such a change would mean public authority interference in the private contractual relationship between manufacturers and notified bodies, with a subsequent administrative burden and cost.
  - Therefore, we strongly suggest reverting to the text of Article 13 paragraph 6 of the current Directive:

    Article 13
    (…)
    "*6. Documents and correspondence relating to the procedures referred to in the abovementioned paragraphs shall be drawn up in one of the official languages of the Member States in which those procedures are being applied or in a language accepted by the notified body*."

- **Annex III, Module EU-type examination: supporting evidence for adequacy of the technical design solution**
  - Decision 768/2008/EC under point 2 of Annex II Module B "EC-type examination" provides for the possibility to carry out EU-type examination in 3 ways. However, the current Directive and the recast proposal under Annex III paragraph 2 provide for the first option only, i.e the traditional production type:

    ANNEX III
    (…)
    "2. EU-type examination shall be carried out with the examination of a specimen, representative of the production envisaged, of the complete product (production type)."
  - Therefore, for the sake of clarity and to avoid misunderstandings, we ask for the **deletion of the last indent of paragraph 3 of Annex III** ("*the supporting evidence for the adequacy of the technical design solution (…) under his responsibility*"). The

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inclusion of this indent is an editorial mistake as it refers to another conformity assessment option foreseen in Decision 768/2008/EC, which however is not applicable to ATEX products.

d. Simple pressure vessels (SPVD): Recast. 'Goods package' – 2011/0350(COD)

- **The alignment of Article 6 of the recast proposal lacks the flexibility provided for in Article R2 of Decision No 768/2008**.
  - In Chapter 2 "obligations of economic operators", *Article 6 of the recast proposal requires that "Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted* ***on the vessel****."*
  - This requirement to affix all these indications on the product itself is not always technically feasible and is disproportionately costly. Therefore, Orgalime requests that the text be aligned as closely as possible with Article R2 of Decision 768/2008/EC, which provides that the requested indications can be provided "**where that is not possible, on its packaging or in a document accompanying the product**".

e. Measuring instruments (MID): Recast. 'Goods package' – 2011/0353(COD)

- **The possibility to use accredited in-house bodies should be reintroduced in the recast proposal**.
  - There is no reason why the recast proposal has deleted the use of accredited in-house bodies as foreseen in the current Measuring Instruments Directive. Decision 768/2008/EC (Article R21) explicitly provides for the possibility to use accredited in-house conformity assessment bodies under modules A1, A2, C1 and C2. The current Measuring Instruments Directive also uses these modules for certain product categories. Therefore, the deletion of these bodies is a change to the technical contents of the current Directive, which goes beyond the alignment with the NLF and is therefore inconsistent with the scope of this recast .
  - Orgalime members have had very positive experience with the use of accredited in-house bodies in the measuring instruments sector and urge the European Parliament and the Council to continue to acknowledge the competence available within the manufacturing sector, all the more so as the competence and necessary level of independence of their in-house laboratories/inspection bodies have been assessed and confirmed by an independent third party, i.e. the national accreditation body.

Therefore we call on re-introducing the possibility to use accredited in-house bodies into all the relevant modules of the recast proposal, as is the case under the current Directive. These bodies have so far carried out their work to the satisfaction of all parties.

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Adviser in charge: Philippe Portalier (firstname.lastname@orgalime.org)