NLF interpretative Fiche

Orgalime Position Paper

Title Short:

Transitional options for Declarations of Conformity under the newly aligned Directives

Fiche Nr: **19**

Subject: Options for the pragmatic handling of issuing the EU-Declaration of Conformity during the transposition period of the Directives aligned with the New Legislative Framework

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Category: Obligations of manufacturers

Legislative references:

This paper refers to the Directives that have recently been aligned with the New Legislative Framework (Decision 768/2008/EU). Therefore, we are using the aligned Low Voltage Directive (2014/35/EU) as an example of the horizontal provisions.

- Where compliance of electrical equipment with the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated by the conformity assessment procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking (Article 6.2).
- The EU declaration of conformity shall state that the fulfilment of the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated (article 15.1).
- By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the electrical equipment with the requirements laid down in this Directive (Article 15.4).
- Member States shall not impede the making available on the market of products covered by (the old) Directive which is in conformity with that Directive and which was placed on the market before 20 April 2016 (Article 25).
- Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with Article 2, the first paragraph of Article 3, Article 4, Articles 6 to 12, Article 13(1), Articles 14 to 25 and Annexes II, III and IV. They shall forthwith communicate the text of those measures to the Commission. They shall apply those measures from 20 April 2016 (Article 26).
- Directive 2006/95/EC is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex V (Article 27).
- The object of the declaration described above is in conformity with the relevant Union harmonisation legislation (Annex IV point 5)

REQUEST

Orgalime requests the European Commission to allow for pragmatic solutions to the question of which Directives should manufacturers indicate on Declarations of Conformity (DoC) issued **during the transposition period**.

This is the period starting from the date of entry into force of the revised Directive (new Directive) and ending with the date of repeal of the existing Directive (old Directive), that is until 19 April 2016.

Such pragmatic solutions are necessary after the alignment of Directives with the New Legislative Framework. This alignment led to a change of the Directives' numbering, but without any changes to their essential requirements. Nevertheless, the Directives' provisions for the transitional period do not contain any statements regarding the version(s) of the Directive(s) to be referenced in the Declarations of Conformity (DoC).

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This can have a significant impact on business because:

- For products manufactured in series, manufacturers would be obliged to issue all DoCs again, within a single day (repeal of old Directives and implementation of new Directives by manufacturers on 20 April 2016). This is logistically impossible to manage for manufacturers with a somewhat larger product range. Moreover, under a number of Directives (e.g. machinery, ATEX, RED), the DoC is required to accompany the product. Manufacturers cannot change DoCs that need to accompany the product "overnight" (within a single day).
- For products manufactured in series, manufacturers usually cannot determine the exact date when a product that has been manufactured and put in stock will be placed on the market. This may happen during the transposition period or just after its expiry. For products falling under Directives requiring the DoC to accompany the product, manufacturers would have to unpack all products in stock just to replace the DoC. It would not be proportionate to do this so as to simply correct the Directive's numbering given that the two Directives have the same essential requirements and thereby the content of the DoC remains correct.

Orgalime suggests allowing manufacturers the flexibility to choose between three viable solutions which were used in the past to avoid any significant impact on business:

OPTION 1: EARLY USE OF THE NEW DIRECTIVE'S NUMBER

From the entry into force of a Directive onwards, the manufacturer is allowed to indicate the new Directive number on all DoCs, **provided that the product conforms to the requirements of the new Directive**.

Justification: The new Directive has already entered into force. Therefore, both manufacturers and market surveillance authorities are aware of its numbering and provisions.

This solution facilitates the tasks of manufacturers closer to the transposition date of the new Directive, for example as they might sign the DoC just before the end of the transposition period.

Particularly, in the present case of Directives that have been subject only to alignment with the New Legislative Framework and have not undergone any revision of their essential requirements, it is clear that a product that complies with the old Directive is still compliant with the essential requirements of the new Directive. Therefore, the DoC's content remains correct.

This solution was used for the transposition period of the Low Voltage Directive 2006/95/EC, where it was accepted that from the date on which Directive 2006/95/EC came into force (16 January 2007), all newly issued documents, especially DoCs and technical files, where references are made, should refer to Directive 2006/95/EC. Moreover it was agreed that there is no need to update existing documents, as long as no other corrections are necessary[1].

OPTION 2: USE OF BOTH DIRECTIVES' NUMBERS IN PARALLEL

The manufacturer is allowed to indicate both the number of the 'old' Directive and the number of the 'new' Directive on the DoCs issued during the transposition period, **provided that the product conforms to the requirements of the new and old Directive**.

Justification: DoCs must contain a reference to a valid Directive. By indicating both numbers in the DoC, the manufacturer ensures that at least one of them is valid regardless if the product is actually placed on the market before or after the transposition period.

This solution facilitates the tasks of manufacturers who cannot foresee if the product will be placed on the market before or after the transposition period.

This solution was chosen for the Machinery Directive's transposition period (from Directive 98/37/EC to Directive 2006/42/EC).

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[1] Guidelines for the application of Directive 2006/95, page 16

OPTION 3: ON-GOING USE OF THE OLD DOC

DoCs issued before the date of repeal of the old Directive referring only to the old number are allowed to be maintained and used also for products placed on the market after that date for a reasonable period of time if the product is not technically changed and continues to comply with the unchanged essential requirements.

Justification: As the Directives in question have been subject only to alignment with the New Legislative Framework and have not undergone any revision of their essential requirements, it is clear that a product compliant with the old Directive is still compliant with the essential requirements of the new Directive. Therefore, the DoC correctly states that the fulfilment of the safety objectives has been demonstrated.

This solution was also chosen for the Low Voltage Directive's transposition period (from Directive 73/23/EEC to Directive 2006/95/EC[2]).

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[2] See report of the LVD working party 19 March 2007, p. 2