Position Paper

Brussels, 11 September 2014

Orgalime's views on possible points of misinterpretation to be addressed in a revision of the Blue Guide 2014

INTRODUCTION

This table includes Orgalime's views on the parts of the Blue Guide text that caused diverging interpretations among manufacturers. We consider it essential that these parts should be improved in order for the Blue Guide to serve as a useful guidance document for all interested parties.

This list of comments on the text of the Blue Guide complements the Orgalime's list of horizontal questions on the Directives aligned with the New Legislative Framework. The latter raises points where the legislation may require further clarification. Therefore, we would appreciate and expect the relevant clarifications to be included in the Blue Guide's text.

Orgalime, the European Engineering Industries Association, speaks for 40 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2013 accounted for some €1,800 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.

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	Issue	Reference to Blue Guide 2014	Explanation of problem / need for clarification or modification
Product coverage / making available on the market / placing on the market			
1.	"Offer" considered as "making available / placing on the market"	Sections 2.1, 2.2, 2.3	It is essential to clarify that despite the statements in section 2.1, the concept of making available/placing on the market, as traditionally established (Blue Guide 2000) has **not** changed. Therefore, it is necessary to **modify the relevant parts** in sections 2.2 and 2.3: a simple offer (such as an invitation to purchase) is not considered as making available or placing on the market, but this occurs only when the actual supply or the transfer (whether physical or not) of the product takes place. However, we confirm that the relevant statements in section 2.1, according to which products intended to be placed on the market need to comply with Union harmonisation legislation, unless non-compliance is stated in a clearly visible manner.
2.	Coverage of **components**	Various sections, in particular 2.1, 2.2, 3.5	There are diverging interpretations about the coverage of components by Union harmonisation legislation in several sections. Therefore, clarification is necessary to confirm that there is no change to the current status, which is: ▪ **As a general rule** components are not covered as their integration in other products is not considered as "end-use". Therefore, their supply is not considered as placing on the market.

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			▪ **However**, components are covered where this is foreseen in the relevant piece of legislation or –at least– in the agreed sectorial guide on the application of this legislation. We consider that the described coverage of components is correctly stated in section 2.1. Therefore, the relevant sentences in sections 2.2 and 3.5 should make it clear that they refer only to the pieces of harmonisation legislation that cover components.
3.	Repair and “spare parts”	Section 2.1, page 16, last two paragraphs (incl. footnotes 42 and 43)	It is necessary to clarify the relationship between the statements contained in these paragraphs and the relevant provisions in specific pieces of Union harmonisation legislation that cover spare parts (for example, specific timelines). This should be included both in the Blue Guide and Directive-specific guides, as the general statements in the Blue Guide can be confusing.
4.	Repair and “spare parts”	Section 2.1, page 16	The use of the term “unit” in this context could be inferred as meaning that the replacement of a complete finished product is considered to be a “repair”, and that a brand new replacement product would therefore not be considered as a “new” product. This is a significant change from former Commission positions on this issue, and opens the possibility of selling new finished products that do not comply with current requirements as “replacement units”.

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			Therefore, we suggest replacing the word “unit” with “sub-assembly”.
5.	Confusing wording	Section 2.9, page 23, last paragraph – 5th line	“*In that case information concerning legislation applied should always be listed in the Declaration of Conformity”.* As this wording might be confusing, we suggest that the text could state “*As always, also in that case*”.
Obligations of manufacturers			
6.	CE marking obligation	Section 3.1, 2nd paragraph, page 24, last line: “*with a view to placing it on the market*”.	It should be stressed in the Blue Guide’s text that for certain Directives, such as the Machinery Directive, this applies not only if the product is placed on the market again, but also when a manufacturer redesigns or adapts it for his own use. In this case, it is still necessary to ensure that the product still conforms to legislation and to verify the validity of the CE marking. Therefore, we suggest adding to the end of the paragraph the following: “*or for adapting it for his own use, in the case of products covered by pieces of harmonisation legislation that include own use in their scope”.*
7.	Single contact point	Section 4.2.2.1 states: “*Only one single contact point **in the EU** is allowed.*”	The legal texts of the aligned Directives and Decision 768/2008/EU do not foresee an obligation to establish a single contact point ***within the EU***.

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			Therefore, the text of the Blue Guide should be modified not to describe a more restrictive obligation than the legal text. Manufacturers, whether established within or outside the EU, should not be obliged to establish a single contact point within the EU but should have the opportunity to establish a single contact point either inside or outside the EU. The tasks of a single contact point can be carried out regardless of where it is established.
8.	The requirement to indicate name and address for manufacturers	4.2.2.1 paragraph 2	The text of this paragraph should be deleted so that the Blue Guide would be aligned with Article R2(5) of Decision 768/2008. Currently, this paragraph is more prescriptive than the legal text as it states that the identification elements of a product should "*as a first alternative the information should be on the packaging, as a second alternative on an accompanying document*".
9.	Clarification of notion of "risk"	For example, obligation to immediately inform authorities "*where the product presents a risk*"	It should be clarified that whenever "risk" is used in the Blue Guide in the context of Union harmonisation legislation this refers to the so-called "acceptable risk" which is generally reflected by the state of the art as indicated in standards.

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Obligations of distributors and importers/ roles in the supply chain			
10.	Place of manufacture	Section 4.2.2, page 43, third paragraph	"*This information must however not mislead the end-user and the market surveillance authorities about the place of manufacture and the address of each economic operator".* The "***place of manufacture***" should be deleted. It is not relevant to the conformity of the product (as long as there are no requirements for "country of origin" marking).
11.	Importer's address on the Declaration of Conformity	Section 4.2.2.2, page 44, 1st paragraph, last sentence	This part of the text states that the "information" to be understood as "the address of the importer" should be the same as the one on the declaration of conformity (DoC) and in the technical documentation. However, the address of the importer should not be on such documents. The importer may not be known when the DoC is drafted. Moreover, there might be several importers. Finally, importers should not be mentioned in the technical documentation, because this is the intellectual property of the manufacturer. Therefore, we request the Commission to modify the Blue Guide's text in order to align it with the legal provisions.
12.	Confusing wording	Section 4.2.2.3, page 45, 3rd paragraph, last sentence.	Orgalime suggests that *"is identical to the one used"* should be changed into *"should be"* because it describes an obligation and not a fact.

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Market surveillance			
13.	Powers of market surveillance authorities	Section 7.2, page 83, indents on the middle of the page	It should be clarified under which conditions market surveillance authorities get access to the manufacturer's private premises without prior notification or justification.
Scope of the Blue Guide			
14.	Construction Products Regulation (CPR)	Clause 1.5, page 14	It should be clarified that the Blue Guide provisions may be relevant to construction products / CPR as far as CPR covers the reference provisions and horizontal elements contained in the NLF (manufacturer, placing on the market etc.) even though the CPR is not covered by the Blue Guide.
Product requirements			
15.	Technical Documentation: harmonised standards and risk assessment	1. Footnote 126 2. page 32 second paragraph 3. page 34 last paragraph	The statements regarding risk assessment in these three references could be read in a contradictory way. On page 32 it is correctly stated that risk assessment has to be included in the technical documentation, *"unless risk assessment is included in the harmonised standard. If only part of the harmonised standard is used, then the way risks not covered by it are dealt with, should be documented"*.

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			The formulations in the other references could be interpreted in a way that implies that the manufacturer needs to conduct and document a risk assessment in addition to the risk assessment covered by harmonised standards. We interpret footnote 126 and page 32 in such a way that manufacturers have to check whether the harmonised standards used cover all risks and that they have to conduct and document their risk analysis for the parts that are not covered by the harmonised standards used. Therefore, the text should be modified to avoid any room for diverging interpretations.
16.	Specification on risk analysis	Table on page 35	In general, we would like to state that the Blue Guide reflects different approaches and understandings of risk assessment/analysis and that it is not always clear, which parts of the text are based on which understanding of risk assessment. For example, the table on page 35 shows how risk analysis can be used for choosing the essential requirements applicable to a certain product. This approach is relevant for specific directives only, for example machinery, but cannot be applied to directives providing for more general essential requirements. Therefore, this should be clarified with a footnote.

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Referencing			
17.		Section 4.1.2.2, page 34, footnote 135	In the future, this footnote could refer to the Vademecum for European Standardisation
18.		Section 7.2, page 84, 3rd paragraph, 3rd line footnote 233	The footnote does not belong in this sentence. It would be better placed at the end of the paragraph as it addresses the notified bodies.
19.		Section 7.2, page 84 footnote 235	It would be useful to have this information in the main text where it could be easily brought to the reader's attention rather than it being placed in a footnote.