Position Paper

Brussels, 22 June 2015

Orgalime's priorities for revision of the Blue Guide 2014

INTRODUCTION

Orgalime thanks the European Commission for consulting stakeholders on the ongoing revision of the Blue Guide which we believe is essential as a supporting document in the context of the New Legislative Framework (NLF).

In the present position, developed in the table hereafter, we include Orgalime's list of priorities for the revision of the latest version of the Blue Guide, which was published in 2014. We have tried to provide a solution for most of the points that we consider necessary to revise. Nevertheless, we would need more time to provide suggestions on the interpretation of the definition of "placing on the market" in the light of new e-commerce practices, including the role of fulfilment centres in the value chain.

Orgalime, the European Engineering Industries Association, speaks for 43 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 24 European countries. The industry employs some 10.3 million people in the EU and in 2014 accounted for more than €1,825 billion of annual output. The industry accounts for over a quarter of manufacturing output and a third of the manufactured exports of the European Union.

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1.	Confusing wording	Section 1.2.3, last sentence "*If one element goes missing or is weak, the strength and effectiveness of the entire "quality chain" is at stake".*	We suggest modifying this sentence, as "quality" is not covered by the scope of Union harmonisation legislation, which outlines essential health and safety and other essential requirements, but not obligatory quality levels.
2.	Exclusion of Construction Products Regulation (CPR)	Section 1.5	It should be clarified that some parts of the Blue Guide could be applicable to construction products that fall under the scope of the CPR, because the CPR includes horizontal elements contained in the NLF (such as the definitions of manufacturer, placing on the market etc.).
3.	Coverage of components	Various sections, in particular 2.1, 2.2, 3.5	There are diverging interpretations concerning the coverage of components by Union harmonisation legislation in several sections of the Blue Guide. Therefore, it is necessary to confirm that there is no change to the current status, which is that components are covered by Union harmonisation legislation only where this is foreseen in the relevant piece of legislation. We consider that the coverage of components is correctly stated in section 2.1. However, the relevant statements in section 2.2 should be adapted and amended, while the relevant sentence in section 3.5 could be deleted altogether. In particular:

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			- Section 2.2.: The supply of products ~~for further distribution,~~ **~~for incorporation into a final product.~~** for further processing or refinement ~~with the aim to export the final~~ **of the** product ~~outside the Union market~~ is not considered as making available**.** - Section 3.5: ~~The use of a product as a component to be built into a new product that again is placed on the market is **not considered end-use.**~~
4.	Repair and “spare parts”	Section 2.1, page 16, last two paragraphs (incl. footnotes 42 and 43)	It is necessary to clarify that, in principle, repaired products or products supplied in exchange (referred to as “spare parts” in footnote 42) are not considered as “new” products in the sense of Union harmonisation legislation. Therefore, such products have to comply with the requirements that were applicable to the products they are intended to replace, which is the legislation and state of technology (standards) that were applicable at the time the product to be repaired or exchanged was placed on the market. In this case, manufacturers would have to ensure that these products bear the CE marking, issue a Declaration of Conformity (DoC) referring to the repaired / exchanged product and would be able to use harmonised standards applicable at the time that the initial product was placed on the market. This should also be the basis for judging whether a modified product can still be considered as “similar” or not. Moreover, 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 clarification should be included both in the Blue Guide and Directive-specific guides.

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5.	Repair and “spare parts”	Section 2.1, page 16, Footnote 42	Orgalime strongly supports the statement in this footnote. We believe that, given its importance, it should be included in the main body of the text, rather than in a footnote.
6.	“Offer” considered as “making available / placing on the market”	Sections 2.1, 2.2, 2.3	It is essential to clarify that the concept of making available/placing on the market, in particular in view of the challenges presented by e-commerce. We agree with the statements made in section 2.1 which clarify that products explicitly offered for distribution in a catalogue or by means of electronic commerce have to comply with legislation. However, we are concerned with sections 2.2 and 2.3, that qualify a mere offer of a product as constitutive of its placing or making available on the market, irrespective of whether the product would actually be supplied or transferred (whether physically or legally) to another market operator or its final user. Such interpretation qualifies any presentation of the product in catalogues, websites or advertising campaigns as “making available” this product on the market, without legal evidence of its actual supply (*"which could result in actual supply*"). This interpretation: • would constitute a fundamental change from the interpretation established to date • does not comply with the definition of making available in the NLF • creates inconsistencies in the entire concept of placing on the market, and contradicts other statements made in the Blue Guide 2014 (particularly concerning the list of points in section 2.3, "*Placing on the market is considered not to take place where a product is: (…)"*)

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			• neither does it improve the abilities of market surveillance authorities to face the challenges presented by online trade nor ensures the necessary legal certainty for economic operators. Therefore, we suggest stipulating (as in section 2.1) that products offered through e-commerce and catalogues must be compliant with the relevant EU harmonisation legislation or clearly marked otherwise. We suggest the following wording: **1. Deletion in section 2.2, first paragraph:** *"A product is made available on the market when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. ~~Such supply includes any offer for distribution, consumption or use on the Union market which could result in actual supply (e.g. an invitation to purchase, advertising campaigns).~~* " **2. Deletion in section 2.3, third paragraph:** *"Placing a product on the market requires ~~an offer or~~ an agreement (written or verbal) between two or more legal or natural persons ~~for~~ **on** the transfer of ownership, possession or any other property right concerning the product in question."* **3. Amendment of section 7.2, first paragraph:** *Market surveillance authorities monitor products after they have been placed on the market. **This includes the possibility for market surveillance authorities to carry out control activities regarding products offered for example in sales brochures, advertising campaigns or by means of e-commerce**. ~~Thus~~*

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			Market surveillance does not formally take place during the design and production stages, which is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, ~~*nothing prevents*~~ ***economic operators should collaborate with market surveillance authorities*** ~~*market surveillance authorities and economic operators to collaborate during the design and production phase*~~ *after publishing a product offer. Such collaboration* ~~*may help*~~ ***facilitates*** *taking preventive actions and identifying as early as possible safety and* ***other*** ~~*conformity*~~ ***compliance*** *issues. When performing market surveillance, authorities shall check the* ~~*compliance*~~ ***conformity*** *of the product with the legal requirements applicable at the moment of* ***the*** *placing on the market or, if relevant, putting into service of this product.* ***In the case of market surveillance activities directed against products offered for example in brochures, sales catalogues, advertising campaigns or by means of e-commerce, the economic operators concerned shall provide the information required or shall inform the authorities about the date when the actual supply is intended to take place and shall confirm to the market surveillance authorities that they will provide on reasoned request all information required to demonstrate the conformity of the product.***
7.	Placing on the market in the case of imports / Point in time of fulfilment of importer obligations	Sections 2.3, 2.4	It is important to clarify the point in time at which placing on the market occurs in the cases of products being imported in the European Union from third countries. In particular, it is necessary to clarify whether the product is placed on the market at the time of its release for free circulation by customs, or at the time of supply of the product by the importer to either a distributor or an end-user. Orgalime will suggest a comprehensive solution to this problem shortly.

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8.	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*".
9.	Reasoned request (also relevant obligations for the other economic operators)	Section 3.1 footnote 93	The Blue Guide should clarify in further detail what constitutes a "*reasoned request*" according to which manufacturers would have to provide market surveillance authorities with all the information and documentation necessary to demonstrate a product's conformity. Manufacturers consider that the current statement that the information is necessary for normal market surveillance activities is not a sufficient reason for them to be required to provide this information. On the contrary, authorities should state the specific reasons why such information is necessary and define which parts of the technical file they need.
10.	CE marking obligation	Section 3.1, 2nd paragraph, page 24, last sentence: "*with a view to placing it on the market*".	It should be stressed in the Blue Guide that for certain Directives, such as the Machinery Directive, the obligation to affix the CE marking on the product applies not only if the product is placed on the market again, but also when manufacturers or users redesign or adapt it for their own use. Therefore, we suggest adding to the end of the paragraph the following: "***or for own use, in the case the product is covered by pieces of harmonisation legislation that include own use in their scope***".

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11.	Confusing wording	Section 3.1 *"If the Union harmonisation legislation covers putting into service, **the person**"*	The term “legal or natural person” should be added here to clarify that the obligations may refer to a company putting the product into service.
12.	User instructions and safety information to accompany the product	Section 3.1, page 25, point 4, footnotes 81-83	**1. Scope of application of this obligation:** The Blue Guide should clarify that the cases (scope of application) and the way manufacturers have to comply with the obligation to accompany the product with instructions depends both on the product’s intended use and end-user. In particular: **a. Consumer products** A large number of products are simple for consumers and other end-users to install, use and operate intuitively without user instructions (for example a simple switch). Therefore, the obligation to accompany the product with instructions should be restricted to products for which it can be assumed that consumers and other end-users do not have the knowledge to install, use or operate it. **b. B2B products for use by professionals** In many cases, a professional user has all the necessary knowledge to install, set up and operate the product. Therefore, besides the safety information and warnings on the product, there would be no need for further user instructions.

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			c. Products supplied exclusively for incorporation into another product It should be clarified explicitly that in the case of products supplied to another manufacturer exclusively for incorporation into another product, it is sufficient to ensure that the manufacturer incorporating the product has sufficient information for the product's incorporation. Moreover, the two parties should be allowed to agree on the language of the user instructions and safety information of the final product, as well as the form in which these instructions and information should be provided. **2. Instructions' content** The Blue Guide should clarify that the instructions, which should accompany the product, need to contain only information relevant to compliant installation, use, operation and disposal of the product. In other words, it is necessary to clarify the relationship between the general obligation contained in the list of obligations for manufacturers (and importers) and the specific provisions contained in the essential requirements of some Directives (for example LVD, Article 6 (7) and 8 (4) versus LVD Annex I (1) (a) or EMC, Article 7 (7) versus EMC Article 18 (3)). For example, manufacturers need to know whether the general obligation contained in Article 6 (7) of the LVD is to be applied in accordance with Annex I (1) (a). This would imply that the obligation to provide instructions and safety information is limited to what is required by the essential requirements (for example Annex I (1) (a): "*the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document*").

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			Orgalime considers this as the most reasonable solution, given that instructions would accompany the product and would be translated into a large number of languages. Further information related to the operation of the product and its functionalities, such as an extensive user manual, may be provided on a public website or on any other data storage medium accessible to the end-user.
13.	Instructions and safety information	Section 3.1, page 25, point 4	The Blue Guide should confirm that when products are sold in bulk, namely to professional users, the obligation to accompany the product with instructions applies to the main package and not to each and every product included in the package.
14.	Technical documentation	Section 3.1, page 25, point 5	According to the Blue Guide, the manufacturer shall "**keep** the technical documentation". In the case of private brand production, under which distributors or an importers place a product on the market under their name or trademark, they are to be legally considered as manufacturers. However, they may not be able to have the full technical documentation in their own possession for confidentiality reasons. In that case, they must ensure that the required technical documentation can be made available to the competent national authority upon a reasoned request.

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15.	Sample testing	Section 3.1	The Blue Guide should provide further guidance on how sample testing should be conducted in practice and to what extent. We consider that sample testing should only take place if the manufacturer and/or the importer have reason to believe that the product already placed on the market may no longer be in conformity. Moreover, it should be clarified that in the case of products that cannot be bought back from the market by the manufacturer or the importer, they are not obliged to carry out sample testing. Also, sample testing is not "deemed appropriate" for single unit products.
16.	Confusing wording	4.1.2.2 Role of harmonised standards	Orgalime considers that it would be clearer if the text reads as follows: *Harmonised standards are European standards to which Regulation (EU) 1025/2012 and sectoral Union harmonisation legislation give a special meaning. Harmonised standards remain of voluntary application. However as long as a title of a harmonised standard is not cited in the OJEU, ~~the special role of a harmonised standard is not yet realized~~* ***the harmonised standard does not give presumption of conformity with the essential requirements it aims to cover.***
17.	The requirement to indicate name and address	Section 4.2.2.1 paragraph 2	The text of this paragraph should be deleted, as it is more prescriptive than the legal text (Article R2(5) of Decision 768/2008). In particular, it states that "*as a first alternative the information should be on the packaging, as a second alternative on an accompanying document*". On the contrary, the legal text does not make such a prioritisation.

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18.	The requirement to indicate name and address	Sections 3.1, 3.3; 4.2.2.1 (also relevant for obligations of importers)	According to the Directives aligned with the New Legislative Framework, products should bear the manufacturer's contact details in a language easily understood by end users and market surveillance authorities. Orgalime requests the Commission to clarify which languages can be considered as "easily understood" in this context given that contact details are not as complex to understand as other information, such as instructions for use. We consider that "easily understood" means in this case, "easily read and easily used for postal communication". Therefore, we believe that contact details in Latin characters can be considered as easily understood throughout the internal market. Moreover, it should be clarified that addresses should be kept in their original language, in order to be in line with postal practices. For example, a street's name in Czech should not be translated into English or any other official language of the EU. Finally, for the case of imported products, it is necessary to clarify that the requirement to have the traceability elements on a visible place of the product or its packaging, does not mean that it should be visible by the importer without opening the bulk packaging used only for the products' import. The opposite interpretation would not be practical, as imported products are normally shipped in opaque cardboard packages.
19.	Manufacturers name and trade name on the product	Sections 3.1, 3.3 4.2.2.1	Orgalime requests the Commission to clarify, with the use of examples, that it is sufficient to indicate on the product either the name or the registered trade name or the trademark.

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		(also relevant for obligations of importers)	This is necessary, because the wording of the Directives only states that manufacturers have to indicate on the product "*their name, registered trade name or registered trade mark and the postal address at which they can be contacted*". Moreover, the Blue Guide (Sections 3.1, 3.3) states that manufacturers have "*to indicate the following three elements: their (1) name, (2) registered trade name or registered trade mark and (3) the address at which they can be contacted*". Both these statements do not specify if the product should bear both the name and trade name or only one of these elements. Therefore, it is necessary to clarify that either the name or the registered trade name or the registered trademark along with the address are sufficient elements for the manufacturer's identification. Otherwise, products would bear the same identification element twice as the name and registered trade name are largely identical.
20.	Technical Documentation: harmonised standards and risk assessment	Section 4.1 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.
21.	Standardisation	Section 4.1.2.2, page 34, footnote 135	In the future, this footnote could refer to the Vademecum for European Standardisation
22.	Specification on risk analysis	Table on page 35	In general, we would like to state that the Blue Guide reflects different approaches to 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.

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			Therefore, this should be clarified with a table like the one at the end of this document.
23.	Place of manufacture	Section 4.2.2, page 43, third paragraph	The "*place of manufacture*" in the phrase "*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"* should be deleted. It is not relevant for the product conformity or its traceability to the person liable for its placing on the EU market.
24.	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, there is no requirement for the address of the importer to be on either the DoC or in the technical documentation. The importer may not be known when the DoC is drafted. Moreover, there might be several importers. Therefore, we request the Commission to delete the last sentence of the 1st paragraph: *"… , so this is not necessarily the address where the importer is actually established. ~~The information has to be the same as the one on declaration of conformity and in the technical documentation."~~*
25.	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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26.	Declarations of conformity issued during transitional periods	Section 4.4	The Blue Guide should foresee that during 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), manufacturers would be 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 both the new and the 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).
27.	Reference of the Directive in the Declaration of Conformity	Section 4.4	The Blue Guide should clarify that the provision of the Directives' text requiring the DoC to "*contain the identification of the Union acts concerned including their publication references*" does not oblige manufacturers to add the number of the Official Journal of the European Union (OJEU) in which the Directives were published in the DoC.

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			On the contrary, it should be sufficient to state the Directive's numbering, as this is indicated in the OJEU. This is in line with current practices and is already applied in the Radio Equipment Directive (Annex VI, 2014/53).
28.	Updates of conformity assessment certificates	Section 5.1.3	The Blue Guide should stress that, in cases which involve third party certification bodies, manufacturers should still be able to receive updates of existing conformity assessment certificates on product variations, even after the repeal of revised or aligned Directives, under which the original certificates were issued. More information on this topic is available in Orgalime's NLF interpretative fiche n°20.
29.	Powers of market surveillance authorities	Section 7.2, page 83, indents in 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.
30.	Clarification of notion of "risk"	For example, obligation for manufacturers to immediately inform authorities "where the product presents a risk"	It should be clarified that whenever "risk" is used by Union harmonisation legislation this refers to the so-called "acceptable risk" which is generally reflected by the state of the art as indicated in the relevant harmonised standards. Clarification is also needed as to what an unacceptable risk (triggering the information obligation) or a "serious" risk triggering the notification through RAPEX (as opposed to a "non-serious risk") to the environment, EMC, efficient use of radio spectrum, measurement accuracy would be, and how this should be determined. *[This could also be an important issue for the sectoral guides under the relevant Directives]*

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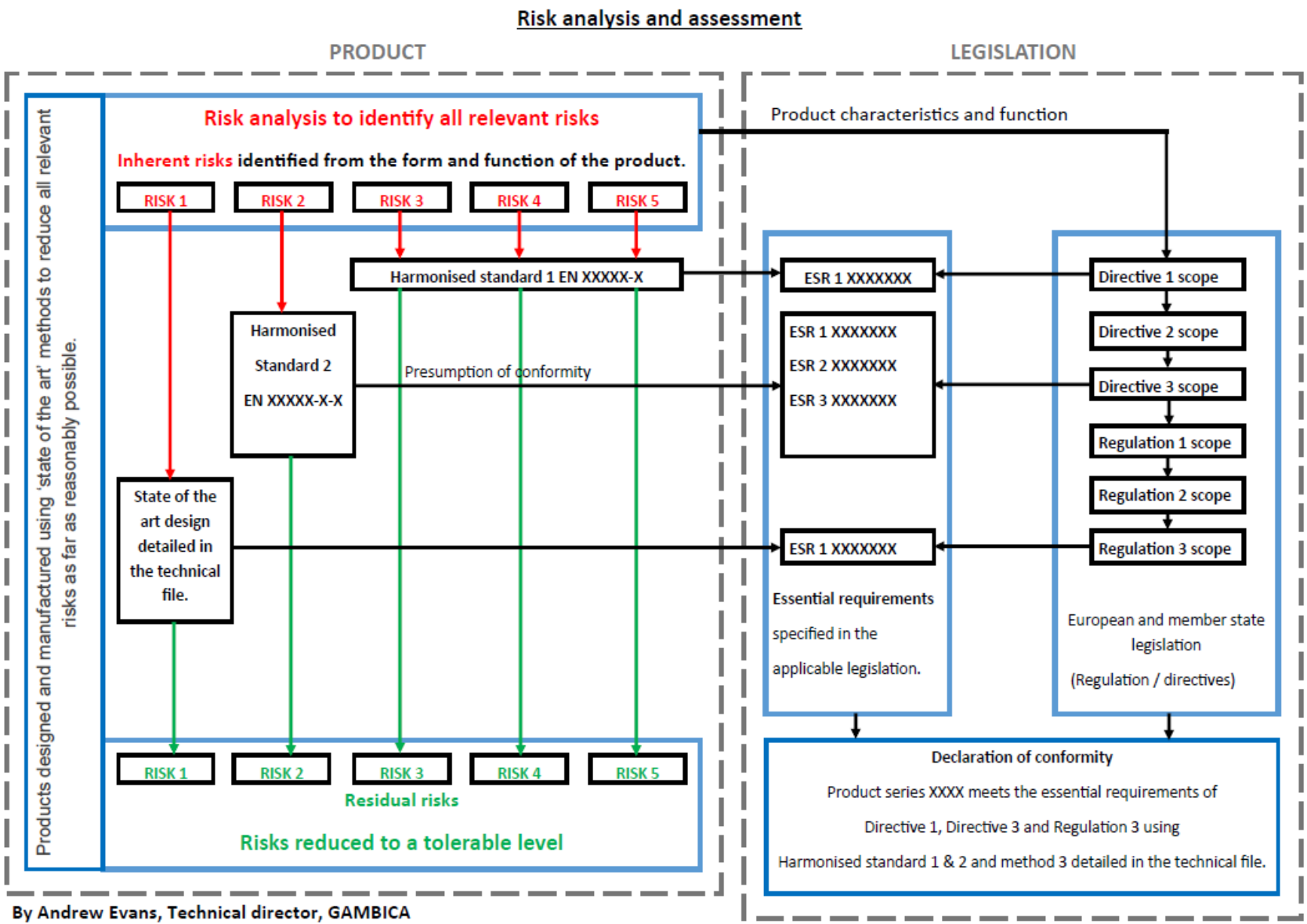
31.	Referencing	Section 7.2, page 84, 3rd paragraph, 3rd line footnote 233	The footnote does not belong in this sentence. It would be better placed at the end of the paragraph as it addresses the notified bodies.
32.	Referencing	Section 7.2, page 84 footnote 235	It would be useful to have this information in the main text where it could be easily brought to the reader's attention rather than it being placed in a footnote.



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