EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

DRAFT GUIDANCE DOCUMENT ON THE LOW VOLTAGE DIRECTIVE TRANSITION FROM 2006/95/EC TO 2014/35/EU

The new **Low Voltage Directive 2014/35/EU**[1] is the result of the alignment of the previous Low Voltage Directive 2006/95/EC to the "New Legislative Framework" (NLF)[2], in particular to Decision No 768/2008/EC[3], as well as to the provisions of the Treaty on the Functioning of the European Union (TFEU) after the Treaty of Lisbon.

Being the result of an alignment and a recast, the main changes in the new Directive 2014/35/EU with respect to the previous Directive 2006/95/EC are quite limited, and do not concern the most substantial characteristics of the act that remain the same: scope, safety objectives, conformity assessment procedure. The main changes are the following:

- *Reference number*: according to the model YYYY / No / UE
- *Definitions*: horizontal additions from the NLF
- *Economic operators* (manufacturers, authorised representatives, importers, distributors) *and their obligations*: more detailed descriptions from the NLF
- *Harmonised standards and presumption of conformity*: reference to Regulation (EU) No 1025/2012 on European Standardisation[4]
- *CE marking*: reference to Regulation (EC) No 765/2008[5]

[1] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits **(**OJ L 96, 29.3.2014, p. 357–374)

[2] See http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

[3] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82)

[4] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12)

[5] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30)

- *Market surveillance and safeguard procedure*: reinforced activities and new simplified procedures (also related to the "Product safety and market surveillance package"[6])

- *Electrical Equipment Committee and implementing acts*: reference to Regulation (EU) No 182/2011[7] ("Comitology") concerning Commission Implementing Decisions on formal objections against harmonised standards and safeguard clauses against products

- *EU declaration of conformity*: more detailed contents, and a model, from the NLF

The new Low Voltage Directive 2014/35/EU is applicable from **20 April 2016**.

This document includes a list of "Frequently Asked Questions and Answers" on the transition to the Low Voltage Directive 2014/35/EU, which covers both "horizontal" and "sectorial" questions, this is to say, those common to all the EU legislation aligned to the "New Legislative Framework"[8] and those specifically related to Directive 2014/35/EU. It reflects the result of ongoing discussions, notably at the workshop on the transition to the new LVD 2014/35/EU held on 27 October 2014.

It should be noted that this document is preliminary, pending the revision of the Blue Guide and the LVD Guidelines. Upon finalisation of the revised Blue Guide (planned for end of 2015) and the LVD Guidelines (planned for mid-2016) the latter documents have to be considered as the main references for the interpretation of horizontal issues related to the New Legislative Framework and the LVD respectively.

[6] See http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

[7] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13)

[8] *Pyrotechnic Articles* Directive 2013/29/EU (applicable 1 July 2015); *Civil Explosives* Directive 2014/28/EU, *Simple Pressure Vessels* Directive 2014/29/EU, *Electromagnetic Compatibility* Directive 2014/30/EU, *Non-automatic Weighing Instruments* Directive 2014/31/EU, *Measuring Instruments* Directive 2014/32/EU, *Lifts* Directive 2014/33/EU, *ATEX* Directive 2014/34/EU, *Low Voltage* Directive 2014/35/EU (applicable 20 April 2016); *Radio Equipment* Directive 2014/53/EU (applicable 13 June 2016); *Pressure Equipment* Directive 2014/68/EU (applicable 19 July 2016) and *Marine Equipment* Directive 2014/90/EU (applicable 18 September 2016). See http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

FREQUENTLY ASKED QUESTIONS ON LVD 2014/35/EU

TOPIC	QUESTION	REPLY
Place on the market **Articles 4, 6, 7, 8**	Difference between **"placing on the market" and "making available on the market"** in the frame of 2014/35/EU (e.g. in Art. 4 making available is mentioned, but for the same activity when the responsibilities of economic operators are covered – e.g. Art. 6, 7, 8 – placing on the market is mentioned)?	'Making available' is the overall concept. Any transfer between economic operators of a product is considered as making available. 'Placing on the market' is a specific case of making available, namely it is the first time that the product is introduced on the market. It is important because at that moment the EU legislation applies. Any subsequent transfer is making available. The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, that operation is labelled in legal terms as placing on the market. Any subsequent operation, for instance, form a distributor to another or to an end-user is defined as making available. *See also § 2.2. "Making available" and § 2.3. "Placing on the market" of the "Blue Guide"*

	In many cases products can be marketed through internet or other means but the product is not physically in the EU. Placing on the market requires the products to be physically in the EU territory?	Union harmonisation legislation applies to all forms of selling. A product offered in a catalogue or by means of electronic commerce has to comply with Union harmonisation legislation when the catalogue or website directs its offer to the Union market and includes an ordering and shipping system. Products offered for sale online by sellers based outside the EU are considered to be placed on the Union market if sales are specifically targeted at EU consumers or businesses. *See also § 2.1. "Product coverage" of the "Blue Guide"*
Manufacturer **Article 6.5**	**Type, batch or serial number:** Does this Article mean that a product specification is required, but not necessarily a serial number? Would there be a way to specify the sequential serial number using a barcode?	The important point is that the numbering must allow making a clear link to the relevant documentation that demonstrates the conformity of the specific type of product, in particular the declaration of conformity. A barcode can also be used if this can reasonably be considered by a manufacturer as an appropriate way to identify and trace his products and to make the link to the relevant documentation. Depending on the product, it is up to the manufacturer to decide whether the identification element should allow the identification of each single product or just the relevant batch or type. But manufacturers should be aware that when public authorities recall products and it is not possible to distinguish between batches or serial numbers, all products of that brand must be removed from the market. The Directive allows placing the information on the packaging or in a document accompanying the electrical equipment if the size or nature of the electrical equipment does not allow it. Of course if the information is

		not visible at a first sight, it must be easily and safely accessible. *See also § 4.2.2.3. "Identification element" of the "Blue Guide"*
Article 6.6	**Name and address on the product** If lack of space, would be possible to indicate the name and address within the product?	The manufacturer must indicate his (1) name, (2) registered trademark and (3) a single contact postal address on the product or, when not possible because of the size or physical characteristics of the product, on its packaging and/or on the accompanying documentation. If the information is put inside the product, it must be easily accessible by the Market Surveillance Authorities, without damaging the product or the need for disassembling it with specific tools. *See also §3.1. "Manufacturer" and §4.2.2.1. "The requirement to indicate name and address of the manufacturer" of the "Blue Guide"*
	Must the information refer to the local distributor or the economic operator placing the product on the EU market?	The information is related to the economic operator that places the product on the market i.e. the manufacturer or importer, not the distributor.
	In the case that a company is based in a third country and in an EU country, is necessary to put the information of both places as manufacturer and importer?	If both, manufacturer and importer belong to the same group or company and if the company based in the EU takes the full manufacturer's responsibility, the indication of the branch based in the EU will suffice to comply with the requirements.

	The postal address in which the manufacturer can be contacted, must be the one of the manufacturer?	Not necessarily. The postal address must be "at which [the manufacturer] can be contacted": this is not necessarily the address where the manufacturer is actually established. This address can for example be the one of the authorised representative or of the customer services. *See also § 4.2.2.1. "The requirement to indicate name and address for manufacturers" of the "Blue Guide"*
	How to implement the requirement that the contact details shall be in a language easily understood?	This provision refers to the use of alphabets. The address details do not have to be translated. The characters of the language must allow identifying the origin and the name of the company. This is not possible with certain alphabets.
Article 6.7	**Instructions and safety information** What does mean 'manufacturer's documentation' within the Low Voltage Directive? As Low Voltage Directive covers safety matters only, may any mandatory documentation relate to safety only?	Instructions and safety information need to be provided, whether the product is intended for consumers or other end-users. The Low Voltage Directive does not make a distinction on who is the user of the product. The documentation should include all the necessary information for the safe use of the product, to enable the consumer to assemble, install, operate, store, maintain, repair, and dispose of the product. It is for the manufacturer to determine the relevant information which should be included in the instructions and safety information for a particular product. One single document can include both safety info and instructions.

	Should each product sold in a bulk contain the instructions and safety information? May documents for products to be used most likely by professionals remain only in English?	In principle, every individual product must be accompanied by the safety instructions but it does not mean that the full instructions must be given in paper. In some specific cases, where several identical products are bundled in a packaging for use in one application (e.g. installation equipment), it is sufficient to accompany the shipping unit with one set of instructions. If another economic operator along the distribution chain dismantles the bundle and sells the products individually, he should ensure that each product individually sold is accompanied by the necessary instructions and safety information. It is the national law that must indicate the languages required and if the use of English is allowed for specific uses. This item will also be clarified in the Blue Guide. *See also § 3.1. "Manufacturer" of the "Blue Guide"*
Article 6.8	The Directive requires that where the electrical equipment presents a risk, manufacturers shall immediately inform the competent national authorities. Which is the threshold of unacceptable risk above which authorities have to be informed?	The acceptable level of risk for a product is determined by the compliance with the essential requirements. The essential requirements of the LVD have not been changed and therefore the previous thresholds for assessing the risks would continue to apply.

Importer **Article 8.2**	"Before placing electrical equipment on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the electrical equipment bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6)" How do we interpret **"the market importers shall ensure"?** Does it mean that the importers must have a copy of the declaration of conformity and the Technical Documentation?	The importer needs to have a copy of the declaration of conformity and has to keep it for 10 years after a product has been placed on the market. The importer does not have to have a copy of the technical documentation but has to ensure that the technical documentation can be made available to the competent national authority upon request. Even if there is no explicit obligation, the importer is advised to require formal assurance in writing from the manufacturer that the documents will be made available when requested by the surveillance authority. But the technical documentation can be given directly by the manufacturer to the surveillance authorities. What is important is that the authorities receive the documentation and that at importer's request the manufacturer provides the information to Member States. The importer also has to check the CE marking, labelling of the product, the identification number of the product, the contact details and that the correct conformity assessment procedure has been carried out. *See also § 3.3 of the Blue Guide on the obligations of importers*
	Should be the product accompanied not only by the instructions for usage and safety but also by the CE declaration of conformity and/or technical documentation?	In the LVD context, the only document that has to accompany the product is the instructions and safety information.

Article 8.4	"Importers shall ensure that the electrical equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned." Can the product be imported with instructions only in English created by the manufacturer, and can the importer himself create a **translation of the instructions** that will accompany the product when is placed on the Union market?	The Directive does not specify which economic operator has to translate the instructions and safety information. Manufacturers, importers and distributors have the obligation to ensure that the product is accompanied by instructions in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. It is for each economic operator which makes available the product in a Member State, to ensure that all the languages are available. Nothing prevents economic operators from reaching contractual agreements on the manner in which they are translated.
	What happens if the product is placed on a market for which the manufacturer has not foreseen a translation?	A manufacturer has a certain set of languages where he intends to ship the product but if it goes somewhere else, importer and distributor must ensure that instructions are translated in the relevant language. It depends on how economic operators are organised by contractual arrangements.
	What happens with bad translations?	According to Article 6.7, instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible and therefore bad translations will be considered as non-compliance.

Distributor **Article 9.2**	"Before making electrical equipment available on the market, distributors shall verify that the electrical equipment bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the electrical equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively." What exactly are the "**required documents**" that are mentioned in this paragraph?	The "required documents" that the distributor needs to make sure that are present are the ones which have to accompany the product, as described in each aligned Directive. In LVD, besides the CE marking which the product needs to bear, the required documents are only the instructions and safety information. The distributor does not have to have a copy of the Declaration of conformity or the Technical Documentation. *See also § 3.4 of the Blue Guide.*
	How do the distributors check if the requirements were met except for the CE marking and the instructions of usage and safety?	The distributor must check that the manufacturer and importer have indicated their name, registered trade name or trademark and the address at which they can be contacted on the product or when not possible because of the size or physical characteristics of the products, on its packaging and/or accompanying documentation and that the product bears a type, batch or serial number or other element allowing the identification of the product.

		The distributor must be able to identify the manufacturer, his authorised representative, the importer or the person who has provided him with the product in order to assist the market surveillance authority in its efforts to obtain the EU declaration of conformity and the necessary parts of the technical documentation. Market surveillance authorities have the possibility to address their request for the technical documentation directly to the distributor. The latter, is however not expected to be in possession of the relevant documentation. Regarding the declaration of conformity, few electrical products fall only under the LVD, normally they are covered by other Directives too. When several Directives regulate a product, the DoC should refer to all of them and the essential requirements. For this reason, when one product is covered by several Directives for which the DoC must accompany the product, if the LVD applies as well, its reference should be included in the 'global' DoC. This should be checked by the importer or distributor. In this regard, when some Directives apply, such as lifts, machinery or R&TTE, the LVD ceases to apply.
Article 9.5	"Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of electrical equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have made available on the market."	There is not specific time limit in the Directive for a "reasonable period". This period has to be assessed by the authorities on a case-by-case basis, taking into account the level of urgency/seriousness of risk and the efforts for the economic operator to follow-up the request. A default period could be e.g. 10 working days, but giving the possibility to shorten it or extend depending of the case. Member States are free to fix a default period in

	What is a **reasonable period** for the distributors to provide the necessary documents, taking in account the fact that even the smallest distributor should provide the information?	their national laws, but there should always be a possibility to shorten or prolong that period.
Harmonised standards **Article 12**	**List of harmonised standards** What would happen with the list of LVD harmonised standards if in the date of applicability of the new Directive new standards are not published?	The LVD mandate requests CENELEC to provide the list of harmonised standards two months before the date of applicability of the new Directive. If the list of harmonised standards referring to the new Directive is not published in time, the mandate and Article 27 of the new LVD state that the references to the repealed Directive shall be construed as references to the new Directive. Therefore, references to the existing LVD would give presumption of conformity with the safety objectives of the new Directive 2014/35/EU, because they remain the same.
	Are LVD harmonized standards going to content an Annex ZA indicating the safety objectives covered by the standard?	The LVD mandate request CENELEC to include the Annex ZA only in new or revised standards, 12 months after the date of application of the new Directive. The annex ZA template will be unified for all New Legislative Framework Directives and ESOs taking into consideration the Directives particularities.

Declaration of conformity **Article 15.2**	**Translation** Is the translation of the EU declaration of conformity manufacturer's responsibility when he markets the equipment under his name or trade mark? Can the importer translate the declaration before he places the product on the market or can the distributor translate it before making it available on the market and provide the translation together with the EU declaration of conformity of the manufacturer which is for example in English?	Union harmonisation legislation does not necessarily specify who has the obligation to translate. It must be considered that, in the LVD, just the manufacturer or the importer has to have a copy of the DoC. There can be a contractual arrangement between the manufacturer and the importer about who does the translation. It should be noted that there is a compulsory template of the DoC in Annex IV, which is translated in the OJEU in all EU languages.
	Must the translations of the declaration of conformity be signed by the manufacturer?	The EU declaration of conformity must be signed by the manufacturer (by an individual working for the manufacturer) or his authorised representative, and the employee's function shall also be indicated. If a translation of the EU declaration of conformity is not signed by the manufacturer, a copy of the original EU declaration of conformity signed by the manufacturer must be provided together with the translated version.
Article 15.1 **Article 15.2**	**Information to be included** Which information must be included in the declaration of conformity?	If a manufacturer produces a declaration of conformity that follows strictly the template set out in Annex IV, he will completely fulfil the requirements of the declaration of conformity. The reference in Annex III does not add any additional requirement. Additional information can be included.

Article 15.3	**Reference to the new LVD** From what date a manufacturer has to mention the new directives for his EU declaration of conformity (DoC)?	Before 20 April 2016 all the EC declarations of conformity for LVD products placed on the EU market must be in line with Directive 2006/95/EC. According to Article 25, products that are already in the distribution chain before 20 April 2016 (including stockpiles: see Recital 36) can continue to be made available on the EU market with this EC declaration of conformity referring to Directive 2006/95/EC as they have already been lawfully placed on the market. Declarations of conformity (EC or EU) remain valid according to the legislation in force when the product is placed on the market (= made available on the EU market for the first time). There is no need to change legislative references in documents accompanying the product. For LVD products placed on the EU market as of 20 April 2016 the EU declaration of conformity must be in accordance to the new LVD 2014/35/EU by that date. Although in the LVD case, the DoC does not have to accompany the product, electrical equipment must comply with other EU legislation and the DoC accompanies often the product. In order to facilitate the transition to the new Directive 2014/35/EU, the EU declaration of conformity can indicate the following: *"The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 2006/95/EC (until April 19th, 2016) and Directive 2014/35/EU (from April 20th, 2016)."*

Equipment presenting a risk **Article 19**	What is the purpose of Article 19 which describes the procedure to deal with electrical equipment presenting a risk at national level?	Article 19 describes the procedure for products presenting a risk. If upon request of the market surveillance authority (MSA), the economic operator agrees to take the necessary corrective action (voluntary measures by the operator), the procedure ends here. In this case, if the MSA consider that the risk goes beyond the national territory, they will inform the Commission and other Member States (MS) of the results of the evaluation and the actions the economic operator intends to take. However, if the economic operator does not take corrective action as requested by the MSA, the MSA shall take appropriate measures against the product (compulsory measures). In this case, the national authorities notify the measure to the Commission and other MS, who have the possibility to object to it during a 3-month period. If no objection is raised, the measure is deemed to be justified. In this case all Member States are obliged to take appropriate action against the product on their territories. If objections are raised, the Commission needs to take a decision to determine whether the measure should be considered as justified or not (Union safeguard procedure in Article 20). The purpose is that restrictive measures against the product are not an unjustified restriction of the free movement of goods. Additionally, is an information-sharing tool between MSAs. This exchange of information, although non-compulsory in the phase of voluntary corrective actions, is also expected to be submitted by the MSA to other MS. The safeguard clause procedure has not changed and must be applied in

	How to compute the "three months" time to raise objections by a Member State or the Commission against a measure taken by a Member State?	limited cases where there is an EU problem and no agreement among MS due to the nature of the risk, the non-compliance or how to deal with that appropriate action. Article 19 must be read in conjunction with Regulation 765/2008, in which Article 20 allows withdrawing a product from the market in case of urgency, for products presenting a serious risk. It is calendar month, the day of notification does not count. For example a notification comes in on 15 September 2015, the three months would hence end on December 16, 24.00h.
Compliant electrical equipment which presents a risk **Article 21**	What is the meaning of Article 21?	The procedure of Article 21 has to be seen as an exceptional case. In principle the requirements of the LVD 2014/34/EU are performance based and technology neutral. However, the Directive takes into account the state of the art when was drafted and usually the internal market Directives have essential requirements more detailed than the LVD. It is possible that with the evolution of time, new technologies and the state of the art, the requirements do not cover all risks, in particular related to new products presenting risks that were not foreseen by the Directive. This is the case envisaged by Article 21. In this case a product may formally comply with the essential requirements but nevertheless present a risk. Authorities must have to possibility to take restrictive measures against the product and this

		procedure allows them to do so. The difference to the "normal" safeguard procedure is that Article 21 deals with "compliant products", while Article 19 deals with products presenting a risk for not complying with the applicable requirements. For the LVD this option will probably never be used due to the broad nature of the safety objectives.
Formal non-compliance **Article 22.2**	"Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the electrical equipment being made available on the market or ensure that it is recalled or withdrawn from the market." How much should the national authorities wait for the non-compliance to continue before taking the appropriate measures to restrict or prohibit the electrical equipment being made available on the market?	It depends on each case but always considering the proportionality principle.
	Is the lack of CE marking a formal non-compliance?	Unless there are reasons to believe that the product presents a risk, there are cases where non-compliance with a number of administrative or formal requirements are defined as formal non-compliance by Article 22. The lack or incorrect affixing of the CE marking is expressly mentioned in Article 22 but it is rarely just a formal non-compliance. In any case, Article 22 does not affect Article 19 (product presenting a risk).

		The CE marking, declaration of conformity and technical files are the cornerstone to place the electrical equipment on the EU market.
Transitional provisions and transposition period **Article 25** **Article 26** **Article 27** **Article 28**	What are the implications of the dates of publication, adoption and applicability?	The most important date is 20 April 2016 from which the Member States have to apply the provisions of the new Directive and to have national laws to transpose it. Until that date, the old Directive is applicable. There are some points in the new Directive that can be already applied because they have not changed. The adoption date is when the text was adopted by the Council of the EU but has no implications. The date of publication indicates the period in which the Directive must be transposed, by 19 April 2016.
	What is the relationship between the dates of application of the LVD, EMC and RED?	See explanatory document in CIRCA BC LVD, R&TTE or EMC. http://ec.europa.eu/growth/sectors/electrical-engineering/ec-support/index_en.htm Closer cooperation between ADCOs will be needed to ensure a good application of the three new Directives.
Technical documentation **Annex III.2**	Directive 2014/35/EU Annex III.2 requires from the manufacturer to include an appropriate risk analyses and evaluation in the technical documentation without	Any conformity assessment procedure would require the manufacturer to start a risk analysis of the specific risks of the product to address them in order to comply with the essential requirements of the Directive because not all products present the same risks. There can be several methods to

	providing any further details. What should be the form and requirements of the risk analyses and how the risk evaluation should be done?	address these risks, such as with the harmonised standards. *Diagram in § 4.1.2.2 of the Blue Guide explains clearly the principle.*
	The new "Blue Guide" explains that if harmonized standards are met, that were created on the basis of a risk analysis, no additional risk assessment must be carried out and no additional documentation must be created. How can we know whether a standard is developed on the basis of a risk analysis?	The Blue Guide statement presupposes a good evaluation of the risks of the product and match between the risks analyses and risks covered by the standards. The fact that harmonised standards are chosen to address the product risks, does not mean that additional risk assessment is not necessary. On the contrary, an analysis of the risks presented by a product by the manufacturer is indispensable. Any conformity assessment procedure requires the manufacturer to start a risk analysis of the specific risks of the product to address them in order to comply with the essential health and safety requirements because not all products present the same risks. This part of the analysis has to be distinguished from part referred to in the Blue Guide: Once these risks are identified and the manufacturer is determining the measures to address those risks in order to comply with the essential requirements he can choose to apply the harmonised standards.