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

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

EMC(23)14 Q&A on EMCD_ FINAL

DRAFT GUIDANCE DOCUMENT ON THE ELECTROMAGNETIC COMPATIBILITY DIRECTIVE TRANSITION FROM 2004/108/EC TO 2014/30/EU

The new **Electromagnetic Compatibility Directive 2014/30/EU**[1] is the result of the alignment of the previous Electromagnetic Compatibility Directive 2004/108/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 2014/30/EU with respect to the previous Directive 2004/108/EC are quite limited, and do not concern the most substantial characteristics of the act that remain the same: scope, essential requirements and 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]

[1] Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility **(**OJ L 96, 29.3.2014, p. 79-106)

[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

- *CE marking*: reference to Regulation (EC) No 765/2008[5]

- *Notified bodies:* interpretation of the requirements and procedures of Decision 768/2008 in the context of EMC.

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

- *Committee on Electromagnetic Compatibility 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 Decision 768/2008

- *EU-type examination certificate:* conditions on validity and date of expiry from the NLF

The new Electromagnetic Compatibility Directive 2014/30/EU is applicable from **20 April 2016**.

This document includes a list of "Frequently Asked Questions and Answers" on the transition to the Electromagnetic Compatibility Directive 2014/30/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 2014/30/EU. It reflects the result of ongoing discussions, notably at the workshop on the transition to the new EMCD 2014/30/EU held on 12 November 2014.

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)

[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

It should be noted that this document is preliminary, pending the revision of the Blue Guide and the EMCD Guidelines. Upon finalisation of the revised Blue Guide (planned for the first half of 2016) and the EMCD 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 EMCD respectively.

QUESTIONS FOR THE WORKSHOP ON THE TRANSPOSTION OF THE EMC DIRECTIVE

TOPIC	ARTICLE	QUESTION	REPLY
Scope	**Article 2** **2. 2**	- What is meant with "*unless the equipment is made available on the market*" in article 2.c? This provision should be clarified in the light of eCommerce: what is applicable for equipment available on other market that the European one? What happens if the same equipment is available and compliant on the European market and the same equipment is also available in a non compliant version on another market outside Europe (knowing that the second one may be less expensive than the first one)?	The article concerning equipment used by radio amateurs has been slightly redrafted to ensure consistency with the terminology used. However, there is no change on the substance. The equipment is exempted unless it is made available on the market. Any equipment that is made available on the market in the EU must be compliant. The Blue Guide clarifies that any product which is sold in any way, including products which are sold online, is placed on the market. This means that the product has to be compliant with EMCD requirements when it is made available for the first time on the Union market.
Scope	**Article 2** **2. 2**	**Custom built evaluation kits** "*Custom built evaluation kits, that are destined to be used by professionals solely at research and development facilities for such purposes*" are excluded from the scope of the aligned LVD,	Under discussion.

		EMC and RED. - Clarification of the criteria and conditions under which custom built evaluation kits would be excluded?	
Scope	**Article 3**	Is a fixed installation placed on the market?	A fixed installation is always just put into service.
Definitions	**Article 3** **3. 1 (15)**	**'Economic operators**' means the manufacturer, the authorised representative, the importer and the distributor - How to deal with distributors which offer/ sell apparatuses where the product is delivered directly from a third country to the buyer of the apparatus? Practically, the 'placing on the market' is executed in this case by each buyer individually. - How to deal with fulfillment centers (like postal or logistic services) who offer services for storing deliveries until the distributor indicates to which address a delivery should be send? This represents a new kind of strategy to avoid that an importer is necessary – or is the postal or logistic service the responsible for placing on the market?	The list of economic operators is exhaustive. An end-user purchasing a product directly from a manufacturer based outside the EU (by internet or other means) cannot be considered as an economic operator and therefore cannot be responsible for compliance of the product. There is no legal obligation for the manufacturer to be established in the EU or to have "a responsible person" inside the EU. In the online context, a manufacturer established outside of the EU can place products on the EU market without an importer or an authorised representative in the EU. However, this does not prevent the authorities from taking action against a non-compliant product; the authorities can and must take action. A market surveillance authority cannot make the end user responsible like an economic operator, but it has to

		If only the name and address of the responsible person for place in the market is missing, can the MSA say that it cannot be placed on the market?	prevent the making available of the product concerned if it is not compliant. In this respect it is for example possible to keep the product at the customs and block it. If the foreign manufacturer is not identified on the product the product is non-compliant and the MSA must take action in order to prevent it from being made available on the market. Concerning fulfilment centres, the Commission will develop guidelines as it is a horizontal issue. It has to be kept in mind that if a product is not compliant, action should be taken.
Making available on the market and/or putting into service	**Article 4**	*Article 4: "Member States shall take all appropriate measures to ensure that equipment is made available on the market and/or put into service only if it complies with this Directive when properly installed, maintained and used for its intended purpose."* We seek clarification whether it was the intention to change current practice, and if not would appreciate clarification in a guidance document.	There is no policy change. Using the term "making available on the market" makes it clear that the product must not only be compliant at the moment of placing on the market, i.e. the first time that the product is made available on the market but also during all subsequent transfers (2nd, 3rd …making available on the market) *See also § 2.2 "Making available" in the Blue Guide.*
Making available on the market	**Article 4** **Article 5**	What is meant with “putting into service”?	As stated in the Blue Guide the putting into service takes place at the moment of first use within the Union

and/or putting into service			by the end user. *For more information see § 2.5 "Putting into service" in the Blue Guide.*
Obligations of manufacturer	**Article 7**	Does the new Directive still cover the putting into service of apparatus manufactured **for own use**?	The concept of own use is only used for certain directives, such as for example the ATEX. The concept of own use refers to the situation when the manufacturer (someone who normally produces the equipment and sells it, as his business activity), installs the equipment and uses it in his own factory. In the EMCD there is no specific provision for manufacturers regarding own use. It was an explicit decision made in the negotiations on the New Legislative Framework not to have all the requirements of the directive applying to "own use" equipment. The directive uses the concept of putting into service with regards to market surveillance in article 4 and free movement in article 5 but not in the context of manufacturers' obligations.
Obligations of manufacturers	**Article 7 7.5**	**Type, batch or serial number:** Is it correct that a product specification is required, but no serial number? Would there be a way to specify the sequential serial	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

		number using a barcode?	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"
Obligations of manufacturers	**Article 7** **7.6**	**Single contact point** According to the Directives aligned with the New Legislative Framework, manufacturers have to affix a postal address that	Single contact points can be established for each product

		indicates a single point at which the manufacturer can be contacted to the product. Can manufacturers establish contact points for each product category? Thereby, they would have the possibility to define specialised contact points for each product category instead of being obliged to have a single point of contact for all their product ranges. **Language in which contact details would be easily understood** According to the Directive, products should bear the manufacturer's contact details in a language easily understood by end users and market surveillance authorities. Which languages can be considered as "easily understood" in this context? **Manufacturer's name and trade name on the product** Is it sufficient to indicate on the product either the name or the registered trade name? 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*".	category. 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. Moreover, the Blue Guide (Chapters 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".
Obligations of manufacturers	**Article 7** **7.6**	**Name and address on the product** Manufacturers/Importers "shall indicate, on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is	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

& **Obligations of importer**	**Article 9** **9.3**	not possible, on its packaging or in a document accompanying the apparatus." - Is this option applicable in cases where the indication is limited by **the size of the apparatus** or are there other reasons where it is not possible?	the size or physical characteristics of the product, on its packaging and/or on the accompanying documentation. *For further information see also § 3.1. "Manufacturer" and § 4.2.2.1. "The requirement to indicate name and address of the manufacturer" of the "Blue Guide".* There are sometimes high tech devices or highly sensitive equipment on which it is not for technical reasons possible to put something on the surface (for example some medical devices). However, this is very restrictive. In the Blue Guide there are some examples of when the product cannot be manipulated, for example because it is "explosive" or if it is not possible under reasonable technical or economic conditions. *See also § 4.5.1 of the Blue Guide on CE marking.*
Obligations of manufacturers	**Article 7** **7.6**	**Name and address on the product** Would it be possible to indicate the name and address inside the product? This information is only really required if a control authority or the operator of the product would like to specifically see this.	The name and address must, as a rule, be affixed to the product. If the information cannot be put on the product, as a first alternative the information should be on the packaging, as a second alternative on the accompanying document. 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".
Obligations of manufacturers	**Article 7 7.7**	**Obligation to accompany the product with instructions** According to the recast aligned Directives, "Manufacturers shall ensure that the [product] is accompanied by instructions and [safety information]". Does the scope of application of the obligation to accompany the product with instructions depend both on the product's intended use and end-user? Need the instructions, which should accompany the product, only contain information relevant to compliant use, operation and disposal of the product?	Instructions and safety information need to be provided, whether the product is intended for consumers or other end-users. The EMC 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. Manufacturers have to look beyond what they consider the intended use of a product and place themselves in the position of the average user of a particular product and envisage in what way they would reasonably consider to use the product. Furthermore, a tool designed and intended to be used by professionals only might eventually also be used by ordinary persons, consequently the design and instructions accompanied must take this possibility into account.

			One single document can include both safety info and instructions. *See also § 3.1 "Manufacturer" of the Blue Guide.*
Obligations of manufacturers	**Article 7** **7. 8**	**Corrective measures** Manufacturers will be required to take corrective actions and to inform the authorities when they have reason to believe that a device that they have placed on the market does not comply with the Directive. What does this mean?	If the manufacturer after having placed a product on the market discovers that the product is not in conformity the manufacturer has to take corrective measures and in the case there is a risk associated with the product he will also have to inform the authorities. The acceptable level of risk for a product is determined by the compliance with the essential requirements. The EMCD assures protection against interference. The "risk" is therefore related to "disturbance" and not the safety.
Authorised representatives	**Article 8**	What is exactly the role of an **authorised representative**? Is an authorised representative responsible (and liable) for compliance with the directives or is the manufacturer still responsible? Which tasks can be performed by an authorised representative? Is there an overview of the tasks?	The Blue Guide clearly explains the role of an authorised representative. *See also § 3.2 "Authorised representative" in the Blue Guide.*
Obligations of importers	**Article 9**	**What is meant by "risk" in 2014/30/EC?** Quoting (just as an example) Article 9 on Obligations of Importers: Where an importer considers or has reason to believe that apparatus is not in conformity with the essential requirements	It is in principle the same question that was already discussed in the context of the obligation of the manufacturers (Article 7.8). When there is a problem

		set out in Annex I, he shall not place the apparatus on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.	with a product put on the market the importer has to take corrective actions; if there is also a risk he must inform the authorities. The acceptable level of risk for a product is determined by the appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The risk is related to the compliance with the essential requirements, which in the case of EMCD concern the risk of electromagnetic disturbance.
Obligations of importers	**Article 9.3**	**Contact details for importer:** If the importer is also the Authorised Representative, can we understand that it is sufficient to indicate only the name and address of that Authorised Representative, because in this case the Manufacturer as well as the importer can be contacted at that address?	If both manufacturer and importer belong to the same group or company, and if the company based in the EU presents itself as the manufacturer, taking the full responsibility for the compliance of the product, the indication of the branch based in the EU will suffice to comply with the requirements. It is not required and also not sufficient to indicate only the name of the authorised representative. *See also Blue Guide, section 4.2.2*
Obligations of importers	**Article 9** **9. 8**	Are the declaration of conformity (DoC) and technical documentation covered by the term “all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of apparatus” in article 9.8	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

		(obligations of importers)? If not what is meant with this?	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. *See also § 3.3 "Importer" in the Blue Guide.*
Obligations of distributors	**Article 10 10. 2**	"Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Annex I, he shall not make the apparatus available on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities." - How should MSA assess if distributor had breached this requirement?	This concerns the general principle of due diligence and it is a matter of case by case assessment. One has to look at what could be reasonably expected from a diligent distributor. It is not possible to provide a list of circumstances in which the distributor should not have put the product on the market, but one example of a situation is when any of the required information is not available. Another example is a situation where there are reports on safety problems with some products in for example the newspaper, which might also indicate that

			the product should not be put on the market. *See also § 3.4 "Distributor" in the Blue Guide.*
Obligations of distributors	**Article 10** **10. 4** **10. 2** **1st §**	"Distributors who consider or have reason to believe that apparatus which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the apparatus presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non compliance and of any corrective measures taken." - How shall a distributor make sure that the corrective measures necessary to bring that apparatus into conformity are taken by manufacturer or importer accordingly?	In most cases the distributor cannot carry out the necessary corrective measures himself. What is expected from the distributor in this case is that he provides the contact details of the importer or the manufacturer so that the authorities can contact them. Article 10 paragraph 5 concerns the same situation as for the importer discussed above under article 9.8. The distributor does not have the obligation to provide the documentation that proves the conformity, the idea is that he should cooperate with authorities as much as possible, and he has to provide what he has in his possession that can demonstrate conformity. Distributors often have test reports, so they have the obligation to provide test reports to authorities.
Presumption of Conformity of equipment	**Article 13**	**List of harmonised standards** What would happen with the list of EMCD harmonised standards if in the date of applicability of the new Directive new standards are not published?	The EMCD 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 45 of the new EMCD state that the references to the repealed Directive shall be construed as references to the new Directive. Therefore, references to the existing EMCD would give presumption of conformity

			with the new Directive 2014/30/EU, because they remain the same.
EU declaration of conformity	**Article 15**	- From what date must the manufacturer mention the new directives for his EU Declaration of Conformity (DoC)? -Due to the different mandatory dates of the EMCD and LVD, and the RED (respectively 2014-04-20, 2016-04-20 and 2016-06-13) it is not clear for the industry how to act in between these different mandatory dates. What are practical options for fulfilling the requirements in this time period?	The new EMCD applies from 20 April 2016 and there is no specific transition period provided as in principle the requirements have not changed. Until 19 April 2016, manufacturers have to comply with the old Directive, meaning that the DoC has to refer to the old Directive. From 20 April 2016 the DoC should refer to new Directive and also comply with the formal requirements on how the new DoC must look like. Although in the EMCD case there are in principle no requirements that the DoC has to be provided with the product, it is however seen very often in practice. In order to facilitate the transition to the new Directive 2014/30/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 2004/108/EC (until April 19th, 2016) and Directive 2014/30/EU (from April 20th, 2016)."*
EU declaration of conformity		-The EMC requires in Article 15 no. 2 that the EU declaration of conformity shall have the model structure set out in Annex IV and shall contain the relevant modules in Annexes II and III. The other	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

		Directive contains similar requirements. To avoid any misinterpretation we would appreciate confirmation that this requirement is fulfilled if the DoC identifies the product as foreseen in item no. 1 and 5 of the DoC template. - The EMC requires in Article 15 (1) and (3) that the EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated. And that the declaration shall contain the identification of the Union acts concerned including their publication references. To avoid and misinterpretation of these requirements 1 and 3 we would appreciate confirmation that this requirement is fulfilled if the DoC includes the reference number of the Directive (i.e. in case of LVD: 2014/35/EC) as foreseen in item no. 6 of the DoC template.	of conformity. The reference to Annex II and III does not add any additional requirement. Additional information can be included. *See also § 4.4 "EU Declaration of Conformity" in the Blue Guide.*
Rules and conditions for affixing the CE marking	**Article 17 17.1**	"The CE marking shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging and to the accompanying documents. " - What is meant with "not warranted on account of the nature" of the apparatus?	It has to be seen on a case by case basis. The Blue Guide provides as an example situations where it is impossible to affix the CE marking to products, as is the case with regards to certain types of explosives. *See also Blue Guide § 4.5.1.4 "Principles of affixing the CE marking".*
Fixed installations	**Article 19 19.2**	Where there are indications of non compliance of the fixed installation, in particular, where there are complaints about disturbances being generated by the installation, the competent authorities of the Member State concerned may request evidence of compliance of the fixed installation, and, when appropriate, initiate an evaluation"." - In the current EMC Directive 2004/108/EC the wording of this sentence is slightly different: "initiate an assessment." What is the	There is no difference in content.

		difference between “evaluation” and “assessment” and what is the reasoning for changing the wording?	
Procedures for dealing with apparatus presenting a risk at national level **38**	**Article 38** **38. 1**	"Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the apparatus does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the apparatus into compliance with those requirements, to withdraw the apparatus from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.” and regarding article 38 no. 1 – 4 paragraph: “Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.)” - How should MSA precede the follow up procedure for non-compliant apparatus in the future?	Article 38 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. The market surveillance authorities shall inform the notified body accordingly. Moreover, if the MSA consider that the risk goes beyond the national territory, they will inform the Commission and other Member States 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 39). The purpose is that restrictive measures against the product are not an unjustified restriction of the free movement of goods. Additionally, it is an information-sharing tool between MSAs. This exchange of information is also useful in the "voluntary phase". The safeguard clause procedure has not changed and must be applied in limited cases where there is an EU problem and no agreement among Member States due to the nature of the risk, the non-compliance or how to deal with that appropriate action. Article 38 must be read in conjunction with Regulation 765/2008, in which Article 39 allows withdrawing a product from the market in case of urgency, for products presenting a serious risk. *See also Blue Guide § 7.3.5 "Market surveillance procedures" (n.b. this section may be moved to a later point in the anticipated 2016 revision of the Blue Guide).*

	Article 38 38. 1 **3rd §**	"The market surveillance authorities shall inform the relevant notified body accordingly." - How should the relevant notified body be informed?	The notified body only needs to be informed if it was involved in the conformity assessment.
Procedures for dealing with apparatus presenting a risk at national level	**Article 38 38. 2** **or 1** **or 3**	Subparagraph 2 of paragraph 1 has been read in some AdCo's as some kind of voluntary phase of the procedure. The reference to the article 21 of Regulation (EC) No 765/2008 in subparagraph 3, however, suggests that this is not the case. Article 21 describes namely in detail how an official decision should be prepared. Also the word "require" implicates that the paragraph does not describe a suggestion but clearly an obligatory measure. Since an obligation was already set according to paragraph 1 what is paragraph 4 needed for?	This phase is not "voluntary" for authorities. However, it is still the phase when manufacturers can take voluntary action. Where the relevant economic operator does not take voluntary action, article 38.4 obliges the market surveillance authorities to inform the Commission and other Member States, without delay, of provisional measures to prohibit or restrict the apparatus's being made available on their national market, to withdraw the apparatus from that market or to recall it, taken in accordance with article 38.4. Article 38 must be read in conjunction with Regulation 765/2008, in which Article 39 allows withdrawing a product from the market in case of urgency, for products presenting a serious risk. With regards to safeguard procedures, the Commission will provide horizontal guidelines how this procedure should be applied as wells as on the use of ICSMS to that end. *See also Blue Guide § 7.3.5 "Market surveillance procedures"(n.b. this section may be moved to a later*

			point in the anticipated 2016 revision of the Blue Guide).
Formal non-compliance	**Article 40** **40. 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 apparatus being made available on the market or ensure that it is recalled or withdrawn from the market. "Formal non-compliance" - Article 38 and 39 depict procedures for dealing with apparatuses that present a risk .Are the formal non-compliances named under article 40 no. 1 covered by the term "Risk"? Are the procedures described in article 38 and 39 applicable if only formal non-compliances were determined? Or are these formal non-compliances handled as "restricted to their national territory" and hence not covered by information requirement/safeguard clause? Should cases which involve formal non-compliances only be published in ICSMS?	Article 40 is a different procedure designed for products which are non-compliant but do not present a risk. The Blue Guide states that in the case of formal non-compliance the market surveillance authority should first oblige the manufacturer, or the authorised representative, to make the product intended to be placed on the market and, if necessary, the product already on the market, comply with the provisions and to remedy the infringement. If no result can be achieved, the market surveillance authority has to, ultimately, take a further step to restrict or prohibit the placing on the market of the product and, if necessary, to ensure that it is also withdrawn from the market. Any decision taken by national market surveillance authorities to restrict or prohibit the placing on the market or the putting into service, to withdraw or recall the products from the market must state the exact grounds on which it is based. The party concerned – in particular, the manufacturer, or the authorised representative established in the Union – must be notified. They must also be informed about remedies available under the national law in force in the Member State in question, and of the time limits to which such remedies are subjected.

			The Blue Guide further states that unless the matter is urgent (for example the product presents a serious risk), the manufacturer, or the authorised representative established in the Union, should have an opportunity to be consulted in advance, before the competent authority takes action to restrict the free circulation of products. In practice, it should be considered as sufficient when the manufacturer or the authorised representative has been provided with an opportunity to react. An explicit provision to consult has been included in Article 21 of Regulation (EC) No 765/2008, However, it should not delay the proceedings, if the manufacturer or the authorised representative remains passive. Every investigation carried out by authorities has to be documented in ICSMS irrespective of the result of the investigation (e.g. formal non-compliance, non-compliance referring to legislative essential requirements, no non-compliance found etc.) *See also Blue Guide 7.3.6 "Corrective measures – bans – withdrawals – recalls" (n.b. this section may be moved to a later point in the anticipated 2016 revision of the Blue Guide).*
Formal non-compliance **- Missing CE**	**Article 40.2**	- 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 requirements are

marking		- In the past a missing CE mark was a clear indication that the product in question was not produced for the European market. During custom checks a missing CE mark is a clear sign that the product in question cannot receive the permission for free circulation as referred to in article 29 no. 2 of the NLF 765/2008: “Product not in conformity — release for free circulation not authorised — Regulation (EC) No 765/2008”. Will this procedure persists from 2016 onwards?	defined as formal non-compliance by article 40. The lack or incorrect affixing of the CE marking is expressly mentioned in article 40 but it is rarely just a formal non-compliance. In any case, article 40 does not affect article 38 (products presenting a risk). The CE marking, declaration of conformity and technical files are the cornerstone to place products on the EU market. Yes.
Transposition	**Article 44**	The dates of transposition in Directive 2014/30/EU and Directive 2014/53/EU are different (two months in between). The transitional provisions are also different. Is there a legal or practical solution for the problem it causes? (Especially for equipment that comes under the scope of another directive).	See separate document dealing with this question available at http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/native.
Internal production control	**ANNEX II** **no. 3**	“The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s)." - What is an adequate analysis and how should manufacturers meet this requirement? The new "Blue Guide" (European Commission, 2014, page 46) explains that no additional risk assessment must be carried out and no additional documentation must be created, if harmonized standards are met, that were	Any conformity assessment procedure requires the manufacturer to carry out a risk analysis of the specific risks. 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

		created on the basis of a risk analysis.	address the product risks, does not mean that additional risk assessment may not be 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. 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.
EU declaration of conformity	**ANNEX IV**	- What is the difference between Annex IV no. 1 and Annex IV no. 4? - How to interpret Annex IV no. 3? Has this sentence to be stated in the EU DoC or is it information for manufacturers about their role only? - How to interpret Annex IV no. 5? Has this sentence to be stated in the EU DoC (added by the number of applicable European Union harmonization legislation)? Or could also another wording be used if it is followed by the mentioning of the European Union harmonization legislation?	Difference between Annex IV no. 1 and Annex IV no. 4: Annex IV no. 1 requires a number identifying the product. The number does not need to be unique for each product. It could refer to a product, batch, type or a serial number. This is left to the discretion of the manufacturer. No. 4 concerns the identification of the product allowing traceability. This is basically any relevant information supplementary to point 1 describing the product and allowing for its traceability. It may where relevant for the identification of the product contain an image, but unless specified as a requirement in the Union harmonisation legislation this

			is left to the discretion of the manufacturer. Annex IV no. 3: A statement that the declaration is issued under the sole responsibility of the manufacturer. Annex IV no. 5: Point 5 should mention the EMC and any other Union harmonisation legislation the product complies with. *See also § 4.4 Blue Guide "EU Declaration of Conformity".*
General: **Horizontal NLF Issues**		Transitional provisions and transposition period a) Earliest point of time where the new LVD, EMCD, RED can be applied (e.g. after first national transposition, after last national transposition, after a 2-year transposition period , etc). See also Orgalime letter to the Commission dated 2014-07-02 b) For a better understanding, we would appreciate a clarification on the implications of "day when the new Directive is published in OJ", "date when the new Directive is adopted", "date when the new Directive is applied".	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.
Transitional provisions for notified bodies		A notified body is mostly involved with a manufacturers product long before the product is marketed in the EU (e.g. at the development stage, which could be like 6 months before the marketing stage). Can a notified body already offer its service	Notified bodies can issue certificates in accordance with the new EMC Directive 2014/30/EU only from 20 April 2016: no certificate under Directive should be issued

		(and issue an EU type examination certificate) under the new EMCD knowing that by the time the new EMCD is in force they will be notified and listed in NANDO? Can we organise notification in such a manner that notified bodies are in business long before the actual operational time of the new EMCD?	before 20 April 2016. Only bodies notified under Directive 2014/30/EU can issue certificates under the new Directive. For practical purposes, bodies can be notified under the new EMC Directive and can start the preparatory work before that date.
Transitional provisions for notified bodies		To simplify procedures and avoid unnecessary costs is it possible to have all current notified bodies automatically be updated to notified body under the new EMCD (unless they indicate they do not want that) and then in the period from April 2016 to e.g. April 2017 give the Notifying Authorities (and/or Accreditation Bodies) time to check whether those notified bodies are truly ok to be on the NANDO list?	It is important that Member States transpose the new EMC Directive or the parts relevant for the notification into national legislation as soon as possible and in any event well ahead of April 2016, in order to ensure that notifying procedures are completed in time, and notified bodies under the new EMC Directive can start operating as of 20 April 2016.