Position Paper

Revision of the Blue Guide

2020-November-10

Bitkom would like to take the opportunity to provide feedback on the Commission's draft for the revision of the Blue Guide.
From Bitkom's point of view, the Blue Guide is an essential guide for economic actors in Europe.
However, we have some general remarks on the draft and would like to deal specifically with chapters 2.1 and 4.2, as these are of particular relevance to us and require correction.

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General comments

The draft for the revision of the Blue Guide contains various points which are not required by any NLF directive and have no legal basis. A guidance document does not have the purpose of adding new requirements. For example[1]:

- chapter 2.3 (4.6.1.4) the sentence "In addition, if products are sold online, the CE marking and any required warnings, information and labels according to applicable legislation shall be indicated in that website; these items shall be clearly visible in its entirety before the consumer is carrying out the purchase."
- chapter 3.1 Paragraph 11, Point 4: the second to last sentence suggests that manufacturers must ensure that the full documentation must remain accessible for a period of 10 years after the product was placed on the market.

We suggest that before the revision of the Blue Guide, the status of the Guide of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products should be clarified. The Blue Guide should clearly reflect the agreed guidance on Article 4 though as consistency is key to compliance and clear enforcement. Please avoid duplicate or even contradictory requirements.

Another problem that occurs frequently in the document can be traced back to the fact that some points probably refer to very specific directives or regulations that are not applicable to all products, but no reference is made to the respective directives. We suggest adding foot notes for listing such directives and regulations clearly. In depth, however, such topics should not be explained in the Blue Guide but in the vertical guides.

[1] For more examples please refer to the attached table.

Detailed statement on Chapter 2.1

Treating a mere “offer” as “placing on the market” in the sense of implying the point in time of application of the requirements in Union harmonisation legislation leads to legal uncertainties for the economic operator.

We are strongly concerned that the interpretation offered in the present draft of Blue Guide (confirming the statements in the 2016 version) and the market surveillance regulation 2019/1020 would undermine basic, well-established New Legislative Framework (NLF) principles and compromise the effectiveness of market surveillance and enforcement.

NLF legislative obligations for importers of products manufactured in a third country would no longer apply if the products, while still located outside the EU, were to be considered to have already been formally placed on the market by a mere offer (online or in sales brochures etc.) targeted at EU end users.

Products could be manufactured and supplied for an unlimited period of time, without the need to adapt them to new or revised NLF legislation, if only they are offered once (online or through other means of distance sales) to EU end-users.

Furthermore, the draft stated that stand-alone software uploaded in connected products that communicate via certain radio modules can also be regulated by the Radio Equipment Directive via delegated acts and that this Directive requires that specific classes or categories of radio equipment support features ensuring that the compliance of that equipment is not compromised when software is uploaded. These sentences give the impression that Art 3.3i is already in force. This is not the case and therefore the information is misleading.

Detailed statement on Chapter 4.2

The content of this chapter is inaccurate in many parts and should definitely be revised in the light of the legal opinion of the German Federal Ministry for Economic Affairs and Energy[2].

1. It is not the harmonised standard which establishes the legal effect of "presumption of conformity", but the publication of its reference in the Official Journal of the European Union (OJEU).
2. The James Eliott Court Case was related to a special case in the construction product regulation (CPR) sector which is excluded from the Blue Guide. A directive which is not designed in accordance with the NLF and also not covered by the scope of the Blue Guide. There is no basis for the extrapolation that this specific case on non-NLF directive applies to NLF directives. Any conclusions and interpretations of the European Commission from the James Elliot case should be limited to the scope of the CPR.
3. The term 'form part of EU law' is taken outside the particular context of the judgement, including the fact that Article 5 of the directive 89/106 was not applied properly. This is not a general mind-set.
4. "the legal status of harmonised standards as part of EU law" is obviously wrong, as the application of harmonised standard is voluntary under all NLF legal acts.,
5. We do not see the added value of "In the same judgment the Court reiterated the Commission's responsibility in the process of initiating, managing and monitoring of harmonised standards", as its content is already specified in Regulation 1025/2012. The legal opinion mentioned above further concluded that the more the Commission is involved in the standardisation work, the more it becomes liable.
6. Article 10.5 of Regulation 1025/2012 does not mission the European commission exclusively but rather states: "The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request." This is a shared responsibility. Further, the inclusiveness and transparency of the development process are not part of the assessment according to Article 10.5. Requirements for inclusiveness and transparency are laid out in Articles 3-7 of Regulation 1025/2012. These two aspects should not be mixed.
7. We do not support the new clarification that "Harmonised standards developed on the basis of a standardisation request must respect its scope and cannot go beyond this scope." There is no reason why a harmonised standard could not go beyond, and contain additional information/aspects, the indications of the related standardisation request. Also, trying to create such a narrow straitjacket for harmonised standards would not on-

[2] https://www.bmwi.de/Redaktion/EN/Meldung/20200831-legal-opinion-on-the-european-standardisation-system.html

ly result in creating discrepancies between international and European standards (and thus create, unnecessarily, barriers to international trade), but also lead to reducing the value of standards for their users and ultimately to less harmonisation in the market place. The role of standardisation requests, as suggested by this sentence, is in fundamental contradiction with the EU's standardisation strategy itself.

8. The sentence "harmonised standards [...] cannot go beyond this scope" contradicts previous statements in which the Commission confirmed that harmonized standards can specify more than what is requested in the standardisation request and thus more than essential requirements as long as the link between the regulation and the standard is clearly specified in Annex Z.
9. The statement "After this deadline a request (Decision) expires unless its validity is extended by the Commission" in 4.2.3 is false. The standardisation request expires at the expiry date. Extending the validly is only possible by means of a new standardisation request which replaces the original one. Further, any later amendments to an existing request must be adopted through a new standardisation request as well. If a request is not accepted by the ESOs, the request expires.
10. Before officially issuing a standardization request, the Commission shall not only consult Member States and other interested parties, but also the relevant European Standardisation Organizations (ESO)s. This has been specified in the Vademecum.
11. The specifications that "standardisation request must clearly and sufficiently define all requested harmonised standards" (4.2.3, p. 55) and "set a clear expiry date" are neither requested neither by Regulation 1025/2012 nor by court cases. Standardization requests shall clearly indicate what is requested but this does not require a prescriptive list of standards or an expiry date.

Please correct the text accordingly by deleting non-relevant text to NLF and aligning the content with regulation 1025/2012 and the Vademecum. Hereafter Bitkom's proposal for chapter 4.2.2:

4.2.2. HARMONISED STANDARDS IN THE CONTEXT OF UNION LAW

Application of harmonised standards remains voluntary. Only essential requirements of applicable Union harmonisation legislation are legally binding. However, the fact that harmonised standards establish legal effects in order to demonstrate compliance with relevant statutory requirements implies that a harmonised standard becomes part of the EU's regulatory framework.

Harmonised standards as part of EU's regulatory framework make it indispensable that each harmonised standard clearly and sufficiently indicates which parts thereof are rele-

vant from the perspective of the requirements set out in the applicable harmonised Union legislation.

The Commission has responsibility in the process of initiating, managing and monitoring of harmonised standards. The Commission must primarily refer to formal aspects and the completeness and logical consistency of the standard according to Article 10 (5) and (6) of the Standardisation Regulation 1025/2012 and not duplicate the standardisation process or develop their own technical rules.

The ESOs are responsible for the development of standards initiated by a standardisation request.

In its assessment preceding publication of the reference in the Official Journal, the Commission must therefore carry out a comparison of the standard with the standardisation request, which may well be detailed, but must primarily relate to formal aspects, completeness and consistency of the standard[2].

Since Regulation (EU) 1025/2012 also stipulates that harmonised standards shall be market-driven and based on consensus, it is imperative to strike a good balance between the Commission's supervisory duties on the one hand and the autonomy of the ESOs on the other.

In article 8 the Regulation calls for the European standardisation to “include objectives for the international dimension of European standardisation, in support of Union legislation and policies”. Recital 3 calls for coordination with international standardisation (ISO, IEC and ITU) to reinforce the global competitiveness of European industry. To this end, CEN and CENELEC have agreements in place with their international counterparts which allow for a swift adoption of international standards as European standards. This implies that these derived standards have not been developed to only reflect essential requirements of the corresponding EU harmonised legislation. On the other hand, changes to the technical content in the adoption process would break the link with the international standard and the potential benefits for the European industry in global markets. Thus, the Commission, by means of its discretionary powers must carefully assess the draft standards to achieve best as possible both objectives of the regulation: support of essential requirements and maintaining the international dimension of standardisation.

The industry and especially SME have well benefited of the international adoption of standards and their swift European harmonisation and citation in the OJEU. The European manufacturer benefits in the European and the International market without divergence in the technical content.

Bitkom represents more than 2,700 companies of the digital economy, including 2,000 direct members. Through IT- and communication services alone, our members generate a domestic annual turnover of 190 billion Euros, including 50 billion Euros in exports. The members of Bitkom employ more than 2 million people in Germany. Among these members are 1,000 small and medium-sized businesses, over 500 startups and almost all global players. They offer a wide range of software technologies, IT-services, and telecommunications or internet services, produce hardware and consumer electronics, operate in the digital media sector or are in other ways affiliated with the digital economy. 80 percent of the members' headquarters are located in Germany with an additional 8 percent both in the EU and the USA, as well as 4 percent in other regions of the world. Bitkom promotes the digital transformation of the German economy, as well as of German society at large, enabling citizens to benefit from digitalisation. A strong European digital policy and a fully integrated digital single market are at the heart of Bitkom's concerns, as well as establishing Germany as a key driver of digital change in Europe and globally.

Clause/ Subclause	Paragraph/Sentence	Comments	Text proposals
1.4.1.1.	A provision in Union harmonisation legislation should be considered 'specific', and thereby render the corresponding provision of the Regulation (EU) 2019/1020 inapplicable, when it offers an equivalent solution guaranteeing the same level (or a higher level) of protection as their corresponding counterpart in Regulation (EU) 2019/1020. In many cases, however, the market surveillance provisions in Union harmonisation legislation are complementary and do not render provisions of the Regulation (EU) 2019/1020 inapplicable.	Here, clearer guidance would be necessary (and expected) to interpret which provisions in NLF legislation (e.g. those relating to economic operators and their obligations?) are actually more specific (if at all)	This is just a general comment. No concrete proposal at this time as, for this, Guidance on the implementation of the new Regulation on market surveillance and product compliance has to be awaited. Such Guidance should then be included in the revised version of the Blue Guide. This is why we make the general comment that Guidance on the implementation of that Regulation needs to be elaborated first before embarking on a revision of the Blue Guide.
1.7	Legal or administrative	Need legal interpretation if "non-	Legal or administrative action may take place against any person in the supply or

	action may take place against any person in the supply or distribution chain who can be considered responsible for a defective product.	compliant" is the same as "defective". Concern that a product defect which does not affect safety or performance could be within scope, i.e., aesthetic defect/quality deviation.	distribution chain who can be considered responsible for a non-compliant product.
1.8	Guide outline	The Blue Guide should specify if the Food Imitation Directive 87/357/EEC is within or outside of scope.	
1.8 Para.2, 3rd sentence:	"The guide gives guidance for the implementation of the provisions and concepts laid down in the New Legislative Framework as well as for the general application of market surveillance provisions according to Regulation (EU) 2019/1020"	We would need and expect guidance not only concerning the market surveillance provisions of Regulation 2019/1020, but in particular also concerning the provisions in Chapter 2 (Tasks of economic operators)!. A precondition for this is achieved consensus on the Guidelines the EU Commission is issued to draw up concerning Article 4 of the Regulation (Article 42(5) of the Regulation)	Please change "market surveillance provisions according to Regulation (EU) 2019/1020" to "market surveillance provisions and rules and obligations of economic operators according to Regulation (EU) 2019/1020"
2.1	Products offered for sale online or through other means of distance sales are considered to be made available on the market if the offer is targeted at end users in the Union. An offer	The new text will require further refinement or clarification, in particular, how are they defining "if the relevant economic operator directs, by any means, its activities to a Member State"? This should be evaluated on a case by case basis, considering various factors such as language, currency, product description, etc.	Products offered for sale online or through other means of distance sales are considered to be made available on the market if the offer is targeted at end users in the Union. An offer for sale shall be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State, and should be evaluated on a case by case basis.

	for sale shall be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State.		
2.1 Box, 1st bullet; Para. 1, 2nd sentence	"Union harmonisation legislation applies when the product is placed on the Union market and to any subsequent operation which constitutes making available ~~until it reaches the end-user.~~"	We do not agree to the deletion of this part of the sentence as this deletion could lead to the misunderstanding that Union harmonisation legislation would also apply to, and set obligations for, end-users (which is not the case). The term "Community (= Union) harmonisation legislation" is defined in Regulation 765/2008/EU to mean "any Community legislation harmonising the conditions for the marketing of products. " The meaning of the termin "Union harmonisation legislation" must not be modifed by Guidance (to extend to market surveillance and enforcement). In the draft version of the Blue Guide, apparently, a different definition of Union harmonisation legislation is used from the term as defined in Regulation 765/2008!	"Union harmonisation legislation applies when the product is placed on the Union market and to any subsequent operation which constitutes making available until it reaches the end-user."
2.1, various places	Concept of interpreting a mere product offer as "placing on the market"' resp. "making available on the	Treating a mere “offer” as “placing on the market” in the sense of implying the point in time of application of the requirements in Union harmonisation legislation leads to undermining the effectiveness of market	While we confirm that the relevant statements in section 2.1, according to which products intended to be placed on the market need to comply with Union harmonisation legislation, unless non-compliance is stated in a clearly visible manner, we do not support the idea that a mere offer should be treated as "placing on the market" in the sense of implying the point in time of application of the requirements in

	market"	surveillance by de-facto eliminating the importer as one of the major economic operators/responsible persons relied upon in both the NLF and Regulation 2019/1020 (Article 4) and by creating legal uncertainty regarding the application of the sector-specific harmonisation legislation on the part of market surveillance/customs authorities and manufacturers alike. • With regard to the regulatory objectives of both the NLF and the new Regulation 2019/1020 (Article 6, cf. recitals (26), (28), (29) in particular), we believe that this provision has to be so construed that the market surveillance authorities should have the powers to take all necessary measures against economic operators, and notably against fulfilment service providers, already at the stage when a product is offered for supply on the EU market. However, for this, it is neither necessary nor appropriate to resort to a legal fiction and advance the formal point in time of placing a product on the market to the moment the product is offered. • We are strongly concerned that the interpretation offered in the present draft of Blue Guide (confirming the statements in the 2016 version) would undermine basic, well-established NLF principles and compromise the effectiveness of market surveillance and enforcement due to legal	Union harmonisation legislation. Rather, the intention is to provide market surveillance authorities with the means to take appropriate measures against products already at that stage. This should be spelt out in Chapter 7 on market surveillance (as it is a provision relating to market surveillance!) Proposal: delete proposed additional sentences in para. 5 of chapter 2.1: "A product intended to be placed on the Union market, offered in a catalogue or by means of electronic commerce, has to comply with Union harmonisation legislation when the catalogue or website directs targets its offer to the Union market and includes an ordering and shipping system. ~~Products offered for sale online or through other means of distance sales are considered to be made available on the market if the offer is targeted at end users in the Union. An offer for sale shall be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State.~~ Where a product is not intended for the Union market or is not compliant with the applicable Union legislation, this has to be clearly indicated (e.g. by providing a visual warning)."

		uncertainty as to the application of the product-related requirements and obligations contained in sector-specific EU product legislation. Consider for example the following scenarios: (1) NLF legislative obligations for importers of products manufactured in a third country would no longer apply if the products, while still located outside the EU, were to be considered to have already been formally placed on the market by a mere offer (online or in sales brochures etc.) targeted at EU end users. So far, EU product legislation based on the NLF imposes obligations on importers who import products from a third country into the EU and place them on the EU market. However, if merely offering the products (online) were to be understood as resulting in the products already being placed on the EU market, then the NLF importer obligations would no longer apply. The importer "technically" still imports the products, but the related NLF obligations would not apply to him since the products (due to the online offering) would have already been placed on the EU market. Such an interpretation would result in de-facto eliminating the obligations for importers foreseen in the NLF legislation and compromise the entire concept of responsibilities placed on the various	

		economic operators in the supply chain. And it would substantially hamper the effectiveness of market surveillance, which is exactly the regulatory objective of Regulation (EU) 2019/1020 itself. (2) Products could be manufactured and supplied for an unlimited period of time, without the need to adapt them to new or revised NLF legislation, if only they are offered once (online or through other means of distance sales) to EU end-users. One of the NLF principles is that the point in time of placing on the market determines the applicability of the relevant sector-specific legislation. If the mere offering of products, whether already manufactured or not, were to be understood as resulting in them being placed on the EU market, then this would make the products “immune” against new or changed NLF legislation: A manufacturer or importer would rightfully argue that the products only need to fulfil the requirements that were in force when the product type was offered for the first time (online or through other means of distance sales, e.g. sales brochures) to EU end users – later requirements would not apply since the products have already been placed on the market through the earlier offering. Such an interpretation would undermine	

		the NLF principle that the legislative requirements apply to each individual product and that product types manufactured and supplied in the EU over a longer period of time may need to be re-assessed for conformity when new requirements enter into force after that product type was first placed on the market. • In our view, the key for an appropriate understanding and application of Article 6 of the new Regulation 2019/1020 lies in the precise wording of that Article, which does not say that a product is placed on the market by offering it online or through other means of distance sales, but explicitly states that products offered in this way ”shall be deemed” to be made available on the market. With regard to the regulatory objective of Article 6, we believe that this has to be so construed that the market surveillance authorities should have the powers to take all necessary measures against economic operators already at the stage of product offerings in view of their later supply / placing on the market (e.g. requesting compliance documentation, taking restrictive measures for the case that the products concerned are actually supplied as offered etc.). However, for the application of the material and formal	

		requirements and obligations of the sector-specific NLF legislation, the point in time of placing on the market remains the actual “supply for distribution, consumption or use on the Union market” (see definition in Art. 3 (1) of Regulation (EU) 2019/1020 and Art. R1.1 of Decision 768/2008/EC).	
2.1 Para. 9, last sentence	"(...) Also, within the terms of specific Union harmonisation legislation, software may be regarded as a finished product or as a component. “	This sentence is wrong: the specific Union harmonisation legislation referred to in footnotes 49 and 50 (save for the Medical Devices Regulation, i.e. RED and Machinery Directive) does NOT cover software as either finished products or as a component. Rather, the software is an integral part of a product covered by these Directives.	Either delete sentence or limit footnotes to the reference to the Medical Devices Regulation. Amend footnote 49 as follows: [49] Stand-alone software presenting certain features is considered as a medical device under the Medical Devices Regulation (EU) 2017/745. Delete footnote 50.
2.1 Para.11	Issue of "different finished products sold together in the same packaging": "In other cases, different finished products may be sold (.....) (.....), the manufacturer marketing the combination must ensure that the risk assessment of the products included in the package takes into	This (new) paragraph is based on the **fundamental misconception** that the same packaging containing different products would be the criterion to indicate that these are always intended to be marketed as a combination! Manufacturers often market their own products together with suitable third-party accessories (components, but also ready-to-use devices that are covered by a Directive, such as cables). The "same packaging" is not the criterion to indicate that this supply is a "combination" that, as such, falls within the scope of application of Union harmonisation legislation and	In other cases, different finished products may be ~~sold~~ supplied together in the same packaging with each of these products ~~which~~ falling within the scope of a particular piece of Union harmonisation legislation with which they must comply ~~with all the provisions of that legislation, irrespective of how the product is packaged and sold to the consumer~~. If the ~~re are two finished~~ products ~~placed on the market in the same package and~~ are intended to function together, the manufacturer marketing the combination must carry out a specific risk assessment to check whether the combination poses new or increased risks compared to the risks posed by the individual products and assessed by the relevant manufacturers. If so, the manufacturer of the combination will have to the take appropriate measures to reduce, to an acceptable level, the risks posed by the products when used as a combination (as intended or under reasonably foreseeable conditions).

	account the intended use (as well as the foreseeable conditions of use for the safety aspects) and that the relevant products comply with the applicable EU legislation when in operation with each other ."	therefore requires an additional conformity assessment. Rather, the manufacturer of the main product is merely a distributor with regard to the accessories, provided that the products that function together do not present any new hazards. In such cases, iIn addition to the obligations as a distributor, the manufacturer of the main product only has the obligation to check whether the accessories supplied together with the main product are **suitable** for operation with his product in terms of the protection goals of the Directives (safety, radio spectrum, EMC, etc.). For example, checks whether the accessories are designed for the EMC environment class (intended use) for which the products are intended to be used/operated.	
2.1 Para. 13, last sentence	"This would not apply when the modified product is not made available, i.e. it is used exclusively by the person carrying out the modification."	Except in those cases where specific Union harmonisation legislation covers "own use" (e.g. ATEX, Machinery, Pressure Equipment Directives etc.)	We suggest including a footnote to clarify this aspect
2.1 Para. 14, 3rd sentence	Neither the repaired products nor the spare parts used need to undergo conformity assessment again, unless the parts fall themselves within the	The last part of the sentence contradicts the concept of product repairs and the use of spare parts, and is inconsistent with the 2nd sentence of para. 14, which correctly states that "such products do not need to undergo conformity assessment again." This is necessary and justified since the	The last part of the sentence ("unless the parts fall themselves within the scope of a specific piece of Union harmonisation legislation ") should be deleted. Also delete footnote 53.

	scope of a specific piece of Union harmonisation legislation.	original product/part to the repaired/replaced was subject to conformity assessment at the time it was placed on the market. Also, footnote Nr. 53 is misleading as the contents is already implied in the treatment of spare parts to comply with the state of the legislation/state of the art applicable at the time the original product/part was supplied.	
2.1 Para. 15, 1st sentence	"In any case, a modified product sold under the name or trademark of a natural or legal person different from the original manufacturer, should be considered as new and subject to Union harmonisation legislation. The person who carries out important changes to the product carries the responsibility for verifying whether or not it should be considered as a new product in relation to the relevant Union harmonisation legislation."	This statement is correct. However, it mixes up two different issues, i.e. the issue of product modification and the issue of change of manufacturer through e.g. re-labelling. Therefore, the statement could be misleading.	Suggest deleting the sentence.

2.1 Para. 17, 2nd sentence	"As is the case for physical repairs or modifications, a product should be considered as substantially modified by a software change where the software update modifies the intended functions, type or performance of the product and the nature of the hazard has changed or the level of risk has increased because of the software update.“	This is only true insofar as the initial risk assessment has not considered/covered the changed hazards and/or the increased level of risk.	At the end of the sentence, add "unless covered by the initial risk assessment."
2.1 Para. 18, 2nd sentence	"The concept of product safety encompasses protection against all kinds of risks arising from the product, including not only mechanical, chemical, electrical risks but also cyber risks and risks related to the loss of connectivity of devices."	Cyber risks and risks due to loss of connectivity imply wider risks that are not limited to safety-related aspects. As a matter of course, the concept of product safety followed by relevant Union harmonisation legislation only encompasses the safety-related aspects of these risks. This should be clarified in the text.	Complement text as follows: "The concept of product safety encompasses protection against all kinds of risks arising from the product, including not only mechanical, chemical, electrical risks but also the safety-related aspects of cyber risks and risks related to the loss of connectivity of devices."
2.1	The manufacturer of the final product can	While sub-assemblies and components should be compliant with relevant	

	rely on the Declaration of Conformity and conformity assessment of the integrated product to build the Declaration of Conformity, conformity assessment and documentation of the final product. Also, within the terms of specific Union harmonisation legislation, software may be regarded as a finished product or as a component.	legislation, there must be some exception allowed for sub-assemblies and components which do not have safety mechanisms in place until they are integrated into their final product.	
2.1	If there are two finished products placed on the market in the same package and intended to function together which, individually, fall within the scope of a specific piece of Union harmonisation legislation, the manufacturer marketing the combination must ensure that the risk	The highlighted portion could have an impact on how products are “marketed in combination” on detail pages, and when products are suggested to be purchased together. This must be clarified in the guidance or specific exclusions note. The term “foreseeable conditions” needs framing. The GPSD uses the term reasonably foreseeable, which is considered vague and poorly defined, but considered on a case by case basis.	If there are two finished products placed on the market in the same package and intended to function together which, individually, fall within the scope of a specific piece of Union harmonisation legislation, the manufacturer marketing the combination (excluding products which are individually packaged but may be offered together as part of a single purchase) must ensure that the risk assessment of the products included in the package takes into account the intended use (as well as the reasonably foreseeable conditions of use for the safety aspects,)determined on a case by case basis, considering available data) and that the relevant products comply with the applicable EU legislation when in operation with each other.

	assessment of the products included in the package takes into account the intended use (as well as the foreseeable conditions of use for the safety aspects) and that the relevant products comply with the applicable EU legislation when in operation with each other.		
2.1	"The level of safety or other public interest protection required by the specific Union harmonisation legislation continues to be relevant when the product is with the end user during the use of the product as intended."	This is very confusing sentence. We believe the intention was to say that the level of protection as required when the product is placed on the market remains relevant during end-use. But as written it may be understood that the level of protection needs to follow the legislation in force during the end use, which is not correct.	Please substitute “the level of protection as required when the product is placed on the market remains relevant during end-use.” Or similar
2.1	“The end-user is not one of the economic operators who bear responsibilities under Union harmonisation legislation i.e. any operation or	Is not accurate. E.g. “Operation” is not specific enough and is subject to interpretation in this context e.g. modification of the product is a kind of operation. Even if the end is not an economic operator, the end-user has the implicit	Please substitute “The end-user is not one of the economic operators who bear responsibilities under Union harmonisation legislation i.e. any transaction involving the product after the first end-use is not subject to Union harmonisation legislation. Nevertheless, the end-user has the implicit responsibility to read and follow the safety (and other public interest) instructions provided with the product and use the product reasonably to ensure the product remains in compliance with the requirements of the

	transaction by the end-user involving the product is not subject to Union harmonisation legislation."	responsibility to read and follow the safety (and other public interest) instructions provided with the product and use the product within a certain reasonable use (like a good father) for keeping compliance of the product with the requirements of the directive or regulation.	directive or regulation." Or similar.
2.1	"Where a product is not intended for the Union market or is not compliant with the applicable Union legislation, this has to be clearly indicated (e.g. by providing a visual warning)."	Due to the modification in the paragraph, the context of this sentence has changed its meaning. Also, "has to" is a strong requirement which is not based on any legal basis.	Please substitute "Where the catalogue or website clearly mentions (e.g. by providing a visual warning) that the product is not intended for the European Union market; or that the product is not compliant with the applicable Union legislation; and the product is not made available to end-user, this product is not considered made available on the market." Or equivalent.
2.1	"A specific Union harmonisation act may regard components, spare parts or sub-assemblies as finished products **and their end-use may be the assembly or incorporation into a finished product**. Therefore, specific Union harmonisation legislation applies to the products it defines within its scope, irrespective of whether	Bold parts are very subject to interpretation and shall be revised because inaccurate. A component which is not intended to be integrated by end-user is not PoM, and therefore not in scope of the EU legislation. E.g. a radio module not made available to end users for self-integration in a product is not product in scope of NLF regulations. An integrator cannot be considered as an end user, because he's manufacturer of the final product and doesn't use himself the intended use (e.g. radio functionality) of the component for his own use. Such manufacturer integrates that functionality in the final product that will be utilized by	Please substitute "A specific Union harmonisation act may regard components, spare parts or sub-assemblies as finished products **when their assembly with or incorporation into a finished product is intended to be carried out by the end-user**. Therefore, specific Union harmonisation legislation applies to the products it defines within its scope, irrespective of whether they are being supplied on a "business to business" or "business to consumer" context. **When such product is within such scope of specific Union legislation, the usual definition of placing on the market applies**. In consequence, it has to fulfil all the legal requirements that might apply and bear the CE marking at that time. When that final product is placed on the Union market including the integrated product, the final manufacturer is responsible for the compliance of the complete final product with the applicable legislation.", or equivalent Otherwise, in case the text from the draft covers very specific directives or regulations and the above proposal is not relevant, please add a foot note for listing such directives and regulations clearly.

	they are being supplied on a “business to business” or “business to consumer” context. **When a product which is within the scope of specific Union legislation is transferred from its manufacturer to be integrated into another final product, it is placed on the Union market at this moment**. In consequence, it has to fulfil all the legal requirements that might apply and bear the CE marking at that time. When that final product is placed on the Union market including the integrated product, the final manufacturer is responsible for the compliance of the complete final product with the applicable legislation.”	the end-user. E.g. a computer’s motherboard made available to integrators only is not placed on the market (integrators integrates the component into the final product, but don’t put into service the component, i.e. integrator is not the end-user), while the same motherboard made available to end-user (e.g. in consumer shop) is placed on the market (end-user put into service the component for its intended purpose).	

2.1	"Generally, as part of the initial risk assessment, the manufacturer of the final product has obligations to foresee the risks of software integrated in that product at the time of its placing on the market."	We believe "has obligation to foresee" is too strong wording because this is not so obvious in the law.	For “has obligation to foresee” substitute "needs to consider”.
2.1	As is the case for physical repairs or modifications, a product should be considered as substantially modified by a software change where the software update modifies the intended functions, type or performance of the product and the nature of the hazard has changed or the level of risk has increased because of the software update.	The addition is too vague, as it is not clear what threshold would be applied to consider “the nature of the hazard has changed” or “risk increase”. Ultimately, if the physical product should continue to be safe, if the risk increases but the product is still safe, then it is not clear how the product could be considered as substantially modified. An “update of the intended functions” will occur with every software modification, which could change (e.g., decrease) the hazards but have no substantial increase in the risk.	As is the case for physical repairs or modifications, a product should be considered as substantially modified by a software change where the software update has a substantial and material effect on the level of risk.
2.1	“Software updates or repairs could be assimilated to maintenance	The meaning of "*And the nature of the hazard has changed*" is not clear because the sentence is too long and contains many entries.	We suggest splitting the sentence and/or listing entries with bullet points, semi-colon. If “level of risk” covers the intended meaning of “and the nature of the hazard has changed”, delete the last.

	operations provided that they do not modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected. As is the case for physical repairs or modifications, a product should be considered as substantially modified by a software change where the software update modifies the intended functions, type or performance of the product and the nature of the hazard has changed or the level of risk has increased because of the software update [56].”		
2.1	Comment 56: “Please note that to address the issue of software updates and upgrades, the Radio Equipment Directive 2014/53	The comment is obviously too long for a document not addressing radio equipment only.	We suggest to delete, because it´s specific to the RE-D and the relevant Article 3.3. i) is not in force.

	already acknowledges that the compliance of some categories of radio equipment with the essential requirements set out in this Directive may be affected by the inclusion of software or modification of its existing software. The user, the radio equipment or a third party should only be able to load software into the radio equipment where this does not compromise the subsequent compliance of that radio equipment with the applicable essential requirements. To that end, the Radio Equipment Directive foresees the possibility for the Commission to adopt a delegated act requiring certain categories of radio equipment to t support certain features in		

	order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated.”		
2.1	The concept of product safety encompasses protection against all kinds of risks arising from the product, including not only mechanical, chemical, electrical risks but also cyber risks and risks related to the loss of connectivity of devices.		The concept of product safety encompasses protection against all kinds of risks arising from the product, including not only mechanical, chemical, and electrical risks. Cyber risks and risks related to the loss of connectivity of devices, which also can (indirectly) lead to safety issues, should be assessed during the product risk assessment.
2.1	"For stand-alone software, placed as it is on the market or uploaded after the product has been placed on the market, the Union sector-specific harmonised product safety legislation does not generally have specific provisions."	"does not generally have specific provision" implicitly suggests that software is in scope, which is not true for all directives that has equipment (i.e. hardware) in scope only.	For "does not generally have specific provision" substitute "does not generally apply ".

2.1	Certain Union harmonisation legislation, such as in for medical devices, have already explicitly considered some aspects of the emergence of digital technologies, e.g. automated decisions, software as a separate product and connectivity. The concept of product safety encompasses protection against all kinds of risks arising from the product, including not only mechanical, chemical, electrical risks but also cyber risks and risks related to the loss of connectivity of devices. For stand-alone software, placed as it is on the market or uploaded after the product has been placed on the market, the Union sector-specific harmonised	The highlighted portion is introducing "stand-alone" software. While not calling it a product generally, the callout here could suggest movement to try to include such software a s product generally. Cyber risks and loss of connectivity are identified as a safety risk; however, these do not necessarily cause harm.	Certain Union harmonisation legislation, such as in for medical devices, have already explicitly considered some aspects of the emergence of digital technologies, e.g. automated decisions, software as a separate product and connectivity. The concept of product safety encompasses protection against all kinds of risks arising from the product, including not only mechanical, chemical, electrical risks but also other risks which may cause harm. For stand-alone software, placed as it is on the market or uploaded after the product has been placed on the market, the Union sector-specific harmonised product safety legislation does not generally have specific provisions. .

	product safety legislation does not generally have specific provisions. However, certain pieces of Union harmonisation legislation address stand-alone software, for example the Regulation on Medical Devices. Furthermore, stand-alone software uploaded in connected products that communicate via certain radio modules can also be regulated by the Radio Equipment Directive via delegated acts.		
2.1 Last two sentences	Furthermore, stand-alone software uploaded in connected products that communicate via certain radio modules can also be regulated by the Radio Equipment Directive via delegated acts. This Directive requires that specific classes or	These sentences, especially the last one, give the impression that Art 3.3i is already in force. This is not the case and therefore the information is misleading.	The last two sentences incl. footnote 57 shall be deleted.

	categories of radio equipment support features ensuring that the compliance of that equipment is not compromised when software is uploaded.		
2.2	“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 in relation to products already manufactured.”	"supply" is undefined. Needs to be defined and made clear if this means shipment, sale, transfer of ownership etc.	
2.3	For the purposes of Union harmonisation legislation, a product is	The addition must define the various economic roles more clearly, i.e., who can be the one who places the product on the	For the purposes of Union harmonisation legislation, a product is placed on the market when it is made available for the first time on the Union market. This operation may be done by the manufacturer, importer, or vendor.[1]. When a manufacturer or an importer

1 E.g. the Lifts Directive uses the concept of “installer” who also places on the market.

	placed on the market when it is made available for the first time on the Union market. This operation should be done by the manufacturer or by an importer. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, the operation is always labelled in legal terms as "placing on the market". Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.	market? Added the term "vendor" to clarify that it is the economic operator who may be outside of the union who is intending to access the Union market, e.g., overseas seller.	supplies a product to a distributor[2] or an end-user for the first time, the operation is always labelled in legal terms as "placing on the market". Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.
2.3	"Placing on the market is considered not to take place where a product is: • manufactured for one's own use (...);" [....]	In order separate the next sentence: „In general ...."which is the opposite of considering not placing of the market. The exemption related to different directives like machine directive. It is confusing. Needs further clarification.	Placing on the market is considered **not** to take place where a product is: • manufactured for one's **private** use. Some Union harmonisation legislation however covers products manufactured for own use in its scope. In general, where a manufacturer supplies products it manufactures for the use of its own employees, these are supplied for use on the Union market in the context of a commercial activity and thus placed on the market;

2 The distribution chain can also be the commercial chain of the manufacturer or the authorised representative.

	In general, where a manufacturer supplies products it manufactures for the use of its own employees, these are supplied for use on the Union market in the context of a commercial activity and thus placed on the market		In general, where a manufacturer supplies commercial quality products (i.e., not development, test, prototype, etc.) it manufactures for the use of its own employees, these are supplied for use on the Union market in the context of a commercial activity and thus placed on the market;
2.3	“Placing on the market is considered not to take place where a product is: • transferred from the manufacturer in a third country to an authorised representative in the Union whom the manufacturer has engaged to ensure that the product complies with the Union harmonisation legislation;”	"transfer" is undefined. Needs to be defined and made clear if this means shipment, sale, transfer of ownership etc.	
2.3	“Placing on the market is considered not to take place where a product is:	"introduced" is undefined. Needs to be defined and made clear if this means shipment, sale, transfer of ownership etc.	

	introduced from a third country in the EU customs territory in transit, placed in free zones, warehouses, temporary storage or other special customs procedures (temporary admission or inward processing);"		
2.3	When an online operator uses a fulfilment service provider in this manner, by shipping the products to the fulfilment house in the EU the products are in the distribution phase of the supply chain	It should be clearly mentioned; who the legal entity is placing such products on the market so far the placing on the market is dedicated to manufacturers or importers. The obligations for the (non-EU) online operator or the fulfilment service provider remain unclear with regard to placing on the market.	Please clarify the obligations.
2.3	"Products offered for sale via online interfaces[74,75] operated by or on behalf of economic operators based in the EU and giving access to those economic operators' products are considered to have been placed on the Union market,	1. The meaning of "*are considered to have been placed on the Union market, regardless of who placed them on the market*" is unclear. 2. This is too restrictive because some global companies' products not intended for the EU market can be placed on the market by 3rd party without agreement of the manufacturer or any legal entity located in the EU. "*Manufacturer or, the importer*" seems to be too restrictive as foreign distributors selling directly to end	Please correct according to the provided comment. e.g. consider "distant sales", don't restrict responsibility to manufacturer or importer.

	regardless of who placed them on the market (manufacturer or, the importer) (...) The EU manufacturer or importer has already placed them on the market before they were offered for sale online."	users in the EU may be neither manufacturer nor importer established in the EU. This is the specific condition where a distributor located outside the EU is making a product available on the EU market to the end-user (who is not an importer in the sense of NLF despite he/she is the one who pays the customs fees). Such distributor has obligation to ensure that the manufacturer of the product complies with the EU directives & regulations (R5.2 of NLF decision) when they make the product available on the EU market. This shall be reflected in the Guide. 3. There is no reason why such sentence is restricted to online interfaces as same problematic may happens with paper catalogue or phone sales.	
2.3 4.6.1.4	"If products are sold online, the CE marking and any required warnings, information and labels according to applicable legislation should be indicated in that website; these should be clearly visible in its entirety before the consumer is carrying out the purchase." 4.6.1.4 (new sentence):	This is not required by any NLF directive and has no legal basis. A guidance document doesn't have purpose of adding new requirement. In addition, this is not consistent with other kind of shop, e.g. in conventional shop, if product is in a sealed box, the end-user won't have access to such document before buying the box; such requirement doesn't apply to paper catalogue. This is not consistent with the principle that e-labelling is not accepted in the EU. Since the CE marking of products covered	Please delete.

	"In addition, if products are sold online, the CE marking and any required warnings, information and labels according to applicable legislation shall be indicated in that website; these items shall be clearly visible in its entirety before the consumer is carrying out the purchase."	by the relevant directives is a legal requirement and not a seal of approval, it should not have to be shown on websites. There is a risk that the CE mark may be used for advertising purposes, which could lead to confusion for the consumer.	
2.3 Para. 1, 2nd sentence	"Th~~is~~e operation ~~is reserved either forusually~~should be done by the~~a~~ manufacturer or by an importer ~~i.e. the manufacturer and the importer are the only economic operators who place products on the market~~	This proposed new text is misleading. Manufacturer and importer are the only economic operators foreseen in the NLF who place products on the market. The fact that there is an "installer" in the Lifts Directive who places lifts on the market may be seen as an exception or as a specificity of that Directive but should not result in making changes to the overall NLF concept!	Leave text as is (ed. 2016): "The operation is reserved either for the manufacturer or the importer i.e. the manufacturer and the importers are the only economic operators who place products on the market."
2.3 Para. 3, 1st sentence	"Placing a product on the market requires an offer or an agreement (written or verbal) between (...)"	See comments above: Treating a mere “offer” as “placing on the market” in the sense of implying the point in time of application of the requirements in Union harmonisation legislation leads to undermining the effectiveness of market	Delete "offer" to read the sentence as follows: "Placing a product on the market requires ~~an offer or~~ an agreement (written or verbal) between (...)"

		surveillance by de-facto eliminating the importer as one of the major economic operators/responsible persons relied upon in both the NLF and Regulation 2019/1020 (Article 4) and by creating legal uncertainty regarding the application of the sector-specific harmonisation legislation on the part of market surveillance/customs authorities and manufacturers alike.	
2.3 Para. 4, 1st bullet	"(...) In general, where a manufacturer supplies products it manufactures for the use of its own employees, these are supplied for use on the Union market in the context of a commercial activity and thus placed on the market ;"	There is no legal basis whatsoever for the generalization of specific provisions covering "own use" in specific Directives. The provision of products / work equipment for use by employees at work does NOT imply any transfer of ownership as the ownership of the producst remains entirely and exclusively with the employer. The employees do not obtain any kind of ownership or product right. Thus, providing products / work equipment to employees does not imply any "supply" of products (and, in addition, there would be no commercial context) and therefore no making available or placing on the market in the sense of Union harmonisation legislation. Rather, the provision and use of such products by employees is governed by the (EU) occupational health and safety legislation!	Delete the sentence ~~"In general, where a manufacturer supplies products it manufactures for the use of its own employees, these are supplied for use on the Union market in the context of a commercial activity and thus placed on the market ;"~~
2.3	"The physical	This sentence is totally unclear. What	Since the sentence does not carry any added value, but rather creates confusion, we

Para. 7, last sentence	fulfilment to end-users in the EU of an order for a product from a given online seller based outside the EU, including by a fulfilment service provider regardless of whether it is based in or outside the EU, gives irrefutable confirmation that a product is placed on the EU market."	information is it supposed to provide? The interesting question here seems to be at what point in time the placing on the market occurs, in the supply chain scenario. However, this question is not answered.	suggest deleting it.
2.3 Para. 12, 1st sentence	"The actual timing of the placing on the market of these products may take place before or after the offer for sale online is first made and may differ for each individual product sold via the offer. e.g"	This sentence is completely unclear. What is meant by "before or after the offer for sale online"? If it is maintained that an offer of a product (already manufactured) implies placing on the market, then it is not conceivable that placing on the market can take place after the offer for sale online (see also 2nd example further below).	Since the concept does not seem to be thoroughly thought through, we suggest deleting the entire paragraph as it does not provided any additional information.
2.3 Para. 13, 2nd bullet	Some products are shipped from outside the EU directly to the end-user in the EU. These are placed on the market once a specific product already manufactured is	Does this mean that once a product type has been offered online and therefore considered to have been placed on the market, products according to type can be shipped without time limits and without the need for adapations to the current state of the legislation/technology?	Proposal: Delete sentence since the entire concept on placing on the market/making available on the market does not seem to be thoroughly thought thru.

	offered for distribution , consumption or use on the Union market."		
2.4. Para.3, 3rd sentence (and following)	"Therefore, when products are presented to customs under the release for free circulation procedure, they are considered, for the purposes of controls, as being placed on the EU market; the products will thus need to be compliant with the applicable Union harmonisation legislation. However, in practice, the release for free circulation and the actual placing on the market may not take place at the same time. The placing on the market is the moment in which the product is supplied for distribution, consumption or use for the purposes of compliance with Union	We do not support the view taken by the Blue Guide (since its 2016 version) that passing the EU borders should no longer be considered as the legal point in time of placing products on the market. Abandoning the established principle according to which placing on the market in the case of products imported from countries outside the EU takes place at the point in time when a product is released by customs for free circulation within the EU leads to legal uncertainty, which is neither acceptable for economic operators, nor in the interests of effective market surveillance. According to the interpretation proposed by the Blue Guide (since 2016), it "may be the case that the release for free circulation and the placing on the market do not take place at the same time" (and that placing on the market can take place before the release for free circulation!). This: - does not comply with the definitions in the NLF (Regulation 765/2008: "'placing on the market' shall mean the first making available of a product on the Community market"); - creates inconsistencies with the	Delete relevant text of chapter 2.4 para.3 and add following text in para.1: "Union harmonisation legislation applies when the product is made available (or put into service) on the Union market for the first time. In the case of imports, as a rule , the first making available takes place when the product is transferred either from the manufacturer to the importer or directly from the manufacturer to the final consumer or user. This means that the relevant point of time is the release by customs for free circulation on the Union market. It also applies to used and second-hand products imported from a third country (...)"

	harmonisation legislation. Placing on the market can take place before the release for free circulation, for example, in the case of online sales by economic operators located outside the EU, even if the physical check of the compliance of the products can take place at the earliest when they arrive at the customs in the EU."	obligations of importers who, together with the manufacturers, are the economic operators supposed to "place products on the market". However, a product can only once be made available for the first time (which would take place when the product is supplied by the third country manufacturer); - does not provide the necessary legal certainty for economic operators and market surveillance authorities; - disregards the fact that the placing on the market is the decisive criterion to determine the legal basis for the measures taken by customs and market surveillance authorities (it is not sufficient for these to be "based on risk analyses"); - may place EU manufacturers at a competitive disadvantage and compromises the objective of enhancing the enforcement of EU internal market legislation.	
2.4. Para.3, 7th sentence (and following)	"Placing on the market can also take place after release for free circulation, for example, where the products are in the stocks of the importer but are not yet made available, that is, when these products are not	Even if the interpretation of the concept of placing on the market advocated by the Commission/Blue Guide (since 2016) were to be followed, this example is incorrect: in the case of an importer (this, by necessity, implies some form of distance sale), the products would ALWAYS have been offered (in some form) before they are supplied to the importer, and therefore, by necessity, the products will already have been placed	Proposal: Delete sentence since the entire concept on placing on the market/making available on the market does not seem to be thoroughly thought thru.

	yet being supplied for distribution, consumption or use, unless otherwise provided for in the applicable Union harmonisation legislation."	on the market. A suitable example would be the case where the manufacturer established in the EU would have ordered products/components to be manufactured on his behalf and under his name in a third country ("(...) or has a product manufactured (...)"), and these products/components are then delivered to the manufacturer for further processing, integration into final products etc.	
2.5. Para.4, 1st bullet (example)	"The need to demonstrate compliance of products (...) - which have not been placed on the market prior to their putting into service (for example products manufactured for own use) or which (...)"	This example is only true for, and therefore needs to be limited to, those products that are covered by harmonisation legislation that covers "own use" in its scope (e.g. Machinery, ATEX Directives).	Complement the example with text as follows: "which have not been placed on the market prior to their putting into service (for example products manufactured for own use where the applicable Union harmonisation legislation covers own use in its scope)"
2.7	Intended use / misuse	The term 'intended use' is no more used in safety directive, but remains in some other directive (e.g. EMC). In safety directives, the new term is "reasonably foreseeable use", which fits with the current content of clause 2.7. Nevertheless, about "intended use", and particularly for essential requirements	The title should be modified to "Reasonably foreseeable (mis)use and intended use" Please avoid any “reasonably foreseen” or equivalent for defining the term “intended use”.

		linked to the functionalities and performance of the product (such as Annex 1 1b of the EMC directive), some of the content in clause 2.7 is irrelevant because the functionalities and performance are fixed by the design of the product (i.e. as the manufacturer designed the product for), and not by any foreseeable use defined by a third party. Nevertheless, the intended use can be deducted based on the information provided on the accompanying documentation, or eventually the product description.	
2.8.4 Turkey	"In 2006, the EU-Turkey Association Council adopted a new Decision (1/2006), (...)"		Delete “new”.
2.8.4 Turkey	"In the area of standardisation, both CEN and CENELEC granted full membership status to the Turkish Standards Institute (TSE) on 1st January 2012."	Please add the status about ETSI.	
2.8.5.1.1 Para.2, 1st sentence	"In some product areas, Union harmonisation legislation foresees 'responsible persons' who have specific tasks in relation to ensuring continued regulatory	This statement is incorrect. The task of "responsible persons“ under Regulation 2019/1020/EU is NOT to "ensure continued regulatory compliance"! It is the manufacturer alone who is in a position to do this. Rather, it is the task of the "responsible persons" to assist the	Delete text in red and replace with "assist the manufacturer in relation to some of his tasks under Union harmonisation legislation covered by Article 4(5) of Regulation 2019/1020/EU."

	compliance and interfacing with market surveillance authorities. "	manufacturer in relation to some of his tasks under harmonisation legislation and to act as an interface to market surveillance authorities.	
2.8.5.1.2		This is not clear whether “EU notified bodies” includes bodies from foreign countries with Mutual Recognition Agreements (MRAs).	Please clarify in the text that MRAs are considered as EU notified bodies.
2.8.5.1.2	"When a certificate has been transferred, both the EU Declaration of Conformity (drawn up by the manufacturer) and the Notified Body Certificate must be updated accordingly: these documents will need to mention that the certificate is now under the responsibility of an EU Notified Body and indicate **both the old UK and the new EU Notified Body's details / identification numbers**."	Why UK notified body needs to remain on the EU DoC when the EU TEC for EU notified body (or MRA) covers the Product? The EU TEC issued from the EU Notified body is sufficient to get presumption of conformity.	Please delete “and indicate both the old UK and the new EU Notified Body's details / identification numbers”.
2.8.5.2	"More specifically, this means inter alia the following: (...)	According to British communications (https://www.gov.uk/government/publications/moving-goods-under-the-northern-ireland-protocol) a product moving from	For “A product shipped from Great Britain to Northern Ireland is an imported product;” Substitute “A product shipped from Great Britain to Northern Ireland for distribution in the EEA is an imported product;”

	A product shipped from Great Britain to Northern Ireland is an imported product;"	GB to NI and not intended for distribution into the EU market remains in the territory of the UK, and is therefore not importer in the EEA. It is subject to a specific form “digital import declaration”	
2.11	Summary Examples	We absolutely welcome the listing of examples which is very helpful in using the guide.	It would be also helpful to link the clause of the chapter for each example.
2.11 2.	A printer manufactured in China, bought by a Spanish wholesaler, on 15 February 2019 and released for free circulation in the EU on 15 March 2019. In this case, the date of placing on the market is 15 March 2019.	We propose to explain the role of economic operator. Explain your conclusion that the product is placed on the market on the 15 March. Please, refer to the corresponding chapter 2.x and clause.	A printer manufactured in China (Manufacturer outside EU), bought by a Spanish wholesaler (Manufacturer - store brand) , Importer and Distributor?) , on 15 February 2019 and released for free circulation in the EU on 15 March 2019. In this case, the date of placing on the market is 15 March 2019.
2.11		The hypothetical examples should be considered again as some base on assumptions without legal basis and lead to more questions, e.g. 1./5. Is the machine completed or a partly completed machine? 3. Corporate structures and internal relations can be complex and are individual.	The hypothetical examples should be considered again.
3.1 Paragraph 11, Point 4		Second to last sentence suggests that manufacturers must ensure that the full documentation must remain accessible for a period of 10 years after the product was	We suggest deleting this requirement.

		placed on the market; where does this requirement come from? Is there any legal basis for it in NLF Directives?	
3.1 Para. 8, 3rd sentence	"Furthermore he must be in the possession of all documentation (such as the technical documentation including any relevant test reports) and certificates necessary to demonstrate the conformity of the product (...)"	This statement is incorrect and should be aligned with the legislation.	Amend text to read as follows: "Furthermore he draw up and shall keep all documentation (such as the technical documentation including any relevant test reports) and certificates necessary to demonstrate the conformity of the product (...)"
3.1 Para. 11, 4th bullet, 9th sentence	"Unless otherwise provided for in specific legislation, whilst the safety information needs to be provided on paper, it is not required that all the set of instructions is also provided on paper but they (...)"	There is no legal base to require ("needs to") the safety information to be provided in paper form! Rather, and in particular for products to be used exclusively by professionals, such safety information should be provided in formats that are suitable considering the specific use context. Therefore, either no statement concerning the format of the information to be provided should be made, or the statements concerning the possibility to provide the information "in an easily accessible manner", including in electronic or other suitable formats, should be made in general terms and according to the specific use context.	Delete the sentence or provide alternative solutions (for example QR-Code to access safety related information).
3.1 Para. 11,	"However, a paper version should always	This statement should be deleted as there is no legal base for such a requirement.	Delete sentence.

4th bullet, 11th sentence	be available free of charge for the consumers who request it;"		
3.5	Taking into account the variety of fulfilment houses and the services they provide, the analysis of the economic model of some operators and the extent of their activities may conclude that they are also distributors, importers or authorised representatives.	It is not clear what analysis will be doused to determine the status of the economic operator (highlighted section). This needs to be clarified.	
3.6	Based on a reasoned request, make sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks	The highlighted section is not clear. If the obligation is for the manufacturer to take action, there should not also be an obligation for the RSP or FSP to take such action. This sentence should be removed, as it should not matter "who" takes the action, the responsibilities for ensuring it is done are stated above.	Based on a reasoned request, make sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks presented by that product. When the responsible economic operator is an authorised representative or a fulfilment service provider, it does not have to take corrective action or mitigate risk itself, but still needs to ensure that the necessary action is undertaken, e.g. by requesting the manufacturer to follow-up and verify whether it has done so, while communicating all the necessary information to it. Please delete the last sentence.

	presented by that product. When the responsible economic operator is an authorised representative or a fulfilment service provider, it does not have to take corrective action or mitigate risk itself , but still needs to ensure that the necessary action is undertaken, e.g. by requesting the manufacturer to follow-up and verify whether it has done so, while communicating all the necessary information to it. Alternatively, in certain cases, an authorised representative or a fulfilment service provider may be in a position to undertake such action themselves, such as in the case of fulfilment service providers recalling products from		

	end users.		
4.1.1. Para. 3, 3rd sentence	"This analysis implies that the manufacturer should assess all the different elements of the products and determine which Union harmonisation legislation applies to it, and which specific essential requirements as set out therein."	Unclear what is meant by "elements": are these features, functionalities, parts or accessories of the product (or something else)?	Clarify sentence or delete it. Clarify sentence as follows: "This analysis implies that the manufacturer should assess all ~~the different elements~~ the functionalities as well as the intended use of the products and determine which Union harmonisation legislation applies to it, and which specific essential requirements as set out therein."
4.1.1. Para.5, Footnote 201	"Harmonised standards never cover all relevant regulated products, services or regulated essential requirements. This is the case in particularly for innovative new product types."	This statement is both wrong and unnecessary. There are indeed numerous standards listed under the Directives that for specific products do cover all applicable essential requirements"!	Either delete sentence or re-formulate "Harmonised standards **may** not cover all relevant...."
4.2 3rd bullet	"and could become compulsory only on the basis of private contracts between economic operators"	This is irrelevant in this guidance.	Please delete.
4.2 Box, 3. bullet	Standards in general are of voluntary application and could become compulsory only on the basis of private contracts	Wrong wording. compulsory relates to mandatory requirements in legislation	Correct sentence to read: Standards in general are of voluntary application and could become mandatory only on the basis of private contracts between economic operators or, in some cases, their application is made compulsory in legislation.

	between economic operators or, in some cases, are made mandatory in legislation.		
4.2.1.	Title: „DEFINITION OF A HARMONISED STANDARD”	The quoted judgment by the CJEU ("James Elliott") was rendered in a very specific context under the Construction Products Regulation, where, as an exception to all other Union harmonisation legislation, the application of harmonised standards is mandatory since they define the requirements for the products. Since this is a particular case in point, there is still much controversy among lawyers and interested parties as to whether the view that harmonised standards form part of EU law could be transferred to other pieces of Union harmonisation legislation, where there application of harmonised standards is voluntary. Therefore, the title should remain as before.	Change title to read: "Role of harmonised standards"
4.2 5th bullet	Voluntary harmonised standards provide a presumption of conformity with the essential requirements they aim to cover.	It is not the harmonised standard which establish legal effect, but its reference in the Official Journal of the European Union (OJEU).	Please change into: Voluntary harmonised standards, once cited in the OJEU, provide a presumption of conformity with the essential requirements they aim to cover.
4.2.2		The content of this subclause is inaccurate in many parts. 1-It is not the harmonised standard which establish legal effect, but its reference in	Please correct the text properly by deleting non-relevant text to NLF and aligning the content with regulation 1025/2012. 4.2.2. HARMONISED STANDARDS IN THE CONTEXT OF UNION LAW

		the Official Journal of the European Union (OJEU) 2- The James Eliott Court Case was related to a special case in the construction sector which is excluded from the Blue Guide. It is pure extrapolation that this specific case on non-NLF directive applies to NLF directives. 3- The term ''form part of EU law', it is taken outside the particular context of the judgement, including the fact that Article 5 of the directive 89/106 wasn't applied properly. This isn't a general mindset. 4- "the legal status of harmonised standards as part of EU law " is obviously wrong as this is not the harmonised standard which is part of the law, but it's the in the OJEU. 5- We don't see the added value of "In the same judgment the Court reiterated the Commission's responsibility in the process of initiating, managing and monitoring of harmonised standards.", as it matches with the requirements of Regulation 1025/2012. The legal opinion by the German Federal Ministry for Economic Affairs and Energy further concluded that the more the Commission is involved in the standardisation work, the more it becomes liable. 6- Article 10.5 of Regulation 1025/2012 does not mission the European commission	Application of harmonised standards remains voluntary. Only essential requirements of applicable Union harmonisation legislation are legally binding. However, the fact that harmonised standards establish legal effects in order to demonstrate compliance with relevant statutory requirements implies that a harmonised standard becomes part of the EU's regulatory framework. Harmonised standards as part of EU's regulatory framework make it indispensable that each harmonised standard clearly and sufficiently indicates which parts thereof are relevant from the perspective of the requirements set out in the applicable harmonised Union legislation. The Commission has responsibility in the process of initiating, managing and monitoring of harmonised standards. The Commission must primarily refer to formal aspects and the completeness and logical consistency of the standard according to Article10 (5) and (6) of the Standardisation Regulation 1025/2012 and not duplicate the standardisation process or develop their own technical rules. The ESOs are responsible for the development of standards initiated by a standardisation request. In its assessment preceding publication of the reference in the Official Journal, the Commission must therefore carry out a comparison of the standard with the standardisation request, which may well be detailed, but must primarily relate to formal aspects, completeness and consistency of the standard[1]. [1: https://www.bmwi.de/Redaktion/EN/Meldung/20200831-legal-opinion-on-the-european-standardisation-system.html] Since Regulation (EU) 1025/2012 also stipulates that harmonised standards shall be market-driven and based on consensus, it is imperative to strike a good balance between the Commission's supervisory duties on the one hand and the autonomy of the ESOs on the other. In article 8 the Regulation calls for the European standardisation to "include objectives for the international dimension of European standardisation, in support of Union legislation and policies". Recital 3 calls for coordination with international standardisation (ISO, IEC and ITU) to reinforce the global competitiveness of European industry. To this end, CEN and Cenelec have agreements in place with their international

		exclusively only but rather states "(...) The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request." This is a shared responsibility. Further, the inclusiveness and transparency of the development process are not part of the assessment according to Article 10.5. Requirements for inclusiveness and transparency are laid out in Articles 3-7 of Regulation 1025/2012. These two aspects should not be mixed. Legal effects: HS the same legal consequences that apply to all other EU law, and thus ultimately call into question the New Approach. The latter is based precisely on the fact that, **beyond legislative processes**, the essential requirements of harmonisation legislation are specified by harmonised standards of the private standardisation organisations, the application of which is voluntary. Accordingly, the ECJ also assumes that harmonised standards are not acts of an institution, body, office or agency of the Union.	counterparts which allow for a swift adoption of international standards as European standards. This implies that these derived standards have not been developed to only reflect essential requirements of the corresponding EU harmonised legislation. On the other hand, changes to the technical content in the adoption process would break the link with the international standard and the potential benefits for the European industry in global markets. Thus, the Commission, by means of its discretionary powers must carefully assess the draft standards to achieve best as possible both objectives of the regulation: support of essential requirements and maintaining the international dimension of standardisation. The industry and especially SME have well benefited of the international adoption of standards and their swift European harmonisation and citation in the OJEU. The European manufacturer benefits in the European and the International market without divergence in the technical content.
4.2.2 Para. 2	"The legal status of harmonised standards as part of EU law	Unclear: why should the indication of the coverage of the essential requirements be an "indispensible" consequence of the	Clarify sentence as follows: "This analysis implies that the manufacturer should assess all ~~the different elements~~ the functionalities as well as the intended use of the products and determine which Union harmonisation legislation applies to it, and which specific

	makes it indispensible that each harmonised standard clearly and sufficiently indicates which parts thereof are relevant from the perspective of the requirements set out in the applicable harmonised Union legislation. "	"legal status" of harmonised standards. Rather, the need for this is related to their effect of providing a presumption of conformity (if listed), and was acknowledged long before the J. Elliott judgment by the Court.	essential requirements as set out therein. "
4.2.2 Para. 4	"In accordance with this responsibility, the Commission has the obligation to follow the development process of harmonised standards thoroughly and to assess whether they comply with the requirements set out in Union harmonisation legislation and/or standardisation requests in order to ensure that harmonised standards fully comply with the applicable legislation. This does not only include the technical aspects of standards	This statement is a pure Commission interpretation of the CJEU judgment which contains nothing in that regard. In particular, the need for the Commssion to check not only the standards as such but also the process of their drafting (and whether that process was "inclusive and transparent") has no legal basis in Regulation (EU) No 1025/2012. This has been underlined in the recent legal expertise as commissioned by the German Ministry of Economics.	Delete last part of the paragraph.

	but also other elements of Regulation (EU) No 1025/2012, such as whether their development process has been inclusive and transparent."		
4.2.2 Para.6	In its judgment in the Case C-630/16 'Anstar', the Court clarified that 'it is necessary to interpret a harmonised standard in the light of the mandate from which it originates' and that 'the scope of a harmonised standard cannot be interpreted more broadly than that of the mandate on which it is based''. These clarifications highlighted the importance of a clear definition of the scope of standardisation requests, both in term of the substance and in terms of the temporal validity. Harmonised	This is a pure Commission conclusion which not only clearly goes beyond the quoted judgment but also has no legal basis in Regulation (EU) 1025/2012. There is no reason why a harmonised standard could not go beyond, and contain additional information/aspects, the indications of the related standardisation request. Also, trying to create such a narrow straitjacked for harmonised standards would not only result in creating discrepancies between international and European standards (and thus create, unnecessarily, barriers to international trade), but also lead to reducing the value of standards for their users and ultimately to less harmonisation in the market place. The role of standardisation requests, as suggested by this sentence, is in fundamental contradiction with the EU's standardisation strategy itself.	Delete sentence.

	standards developed on the basis of a standardisation request must respect its scope and cannot go beyond this scope.		
4.2.3 1st bullet point	"... after informing and consulting the ESOs, relevant stakeholders' organisations at European level, general public, the Member States and..."	We are not aware that the 'general public' is involved in the consultation for issuing a standardization request. AUWP (art. 8 of Regulation 1025/2012) is also subject to consultation but it does not contain complete and detailed information on each request.	Please delete 'general public' „Suggest amending / completing the sentence marked as follows: after receiving a favourable opinion supported by the majority of the Member States in the 'Committee on Standards"
4.2.3 2nd bullet point	A standardisation request is addressed to one or several ESOs to draft requested documents within a set deadline. After this deadline a request (Decision) expires unless its validity is extended by the Commission (Article 10(1) of Regulation (EU) No 1025/2012).	The introduction of an expiry date is a unilateral EC decision. The standardisation request expires at the expiry date. The deadline for developing the requested standards and the expiry date of the standardization request do not necessarily coincide.	Please delete the 2nd sentence.
4.2.3 4th bullet point	Any later amendments to a Commission's standardisation request (regarding e.g. additional documents	Changes to the standardisation request are only possible by means of a new standardisation request which replaces the original standardisation request. However, it is essential to allow sufficient	Please change into: Any later amendments to a Commission's standardisation request are adopted by a new standardisation request following the same procedure as used for the adoption of the initial request.

	or amending requirements, deadlines for adoption of requested documents or its validity period), are adopted following the same procedure as used for the adoption of the initial request.	flexibility for the work programme of the standardisation request in order to ensure that harmonised standards reflect state of the art.	
4.2.3 5th bullet point	The ESOs have no obligation to accept the execution of a request addressed to them. If a request is not accepted by relevant ESO(s), it may not constitute a basis for any standardisation activities aiming to draft harmonised standards for given domain. However a rejection does not, of course, repeal the Decision itself (Article 10(3) of Regulation (EU) No 1025/2012).	If a request is not accepted by the ESOs, the request expires. The last sentence may create doubts.	Delete the last sentence
4.2.3 2nd paragraph	Prior to this, the Commission services must consult the Member States but	Before officially issuing a standardization request, the Commission shall not only consult Member States and other interested parties, but also the relevant	Please change into: Prior to this, the Commission services must consult the Member States, the relevant ESO(s) but also other interested parties

	also other interested parties	European Standardisation Organizations (ESO)s. This has been specified in the Vademecum.	
4.2.3 3rd paragraph	The standardisation request must clearly and sufficiently define all requested harmonised standards in order to enable the European standardisation organisations to establish in harmonised standards a clear link with the scope of the standardisation request. The list of requested harmonised standards must be based on prior consultation of the relevant stakeholders, in particular the European standardisation organisations.	The definition of all requested harmonised standards is neither requested by Regulation 1025/2012 nor by court cases. Standardization requests shall clearly indicate what is requested but this does not require a prescriptive list of standards or an expiry date. The standardisation request should allow sufficient flexibility for developing/ amending/revising harmonised standards in order to reflect state of the art.	Please replace by: The standardisation request must clearly and sufficiently define what is requested.
4.2.3 4th paragraph	The standardisation request must set a clear deadline for the availability of each requested deliverable.	An expiry date for standardization requests is neither requested by Regulation 1025/2012 nor by court cases. Legislation to be supported by the requested standards does not include an expiry date	Please replace by: The standardisation request must set a clear deadline for the development of the requested deliverables.

	Further to the deadline for the availability of each requested deliverable, the standardisation request has to set a clear expiry date beyond which the standardisation request cannot serve as a basis for development of the requested deliverables. If needed, both the deadline for the availability of each requested deliverable and the expiry date can be extended through an amendment to the initial standardisation request.	either. The introduction of an expiry date could harm the regular revision cycle of standards, that ensures the state of the art. The standardisation request should allow sufficient flexibility to extend the deadline for developing harmonized standards without the need for a new standardisation request.	
4.2.3 5th paragraph	When a harmonised standard has been adopted (ratified) by the European standardisation organisation(s) before the expiry date of the standardisation request, it will be possible to publish the	An expiry date for standardization requests is neither requested by Regulation 1025/2012 nor by court cases. Legislation to be supported by the requested standards does not include an expiry date either.	Please change into: When a harmonised standard has been made available by the European standardisation organisation(s), it will be possible to publish the reference thereof in the Official Journal of the European Union – provided conditions set out in Article 10(6) of Regulation (EU) No 1025/2012 are fulfilled.

	reference thereof in the Official Journal of the European Union – provided conditions set out in Article 10(6) of Regulation (EU) No 1025/2012 are fulfilled - even after the expiry date of the standardisation request.		
4.2.3 6th paragraph	Before the preparation of a standardisation request to develop harmonised standards, a relevant Union harmonisation legislation which foresees the use of harmonised standards as a means to comply with essential or other legal requirements should be adopted or under preparation.	How can the standardisation request (being a legal act) and the standards requested therein refer to legislation under preparation? This would not provide legal certainty. Clarification in a footnote is not sufficient in this context.	Please replace by: Before issuing a standardisation request to develop harmonised standards, a relevant Union harmonisation legislation which foresees the use of harmonised standards as a means to comply with essential or other legal requirements shall be adopted. Delete the footnote.
4.2.4. 5th paragraph	The Commission may also refuse to publish references of such standards in the OJEU or, if publication in the OJEU was already done, it may take its	This sentence contradicts applicable EU law (see art 11 of reg 1025/2012). For the withdrawal of references to an harmonised standard from the OJEU, the Commission cannot act on its own initiative. It may only act when a Member State or the European Parliament formally	Delete the sentence.

	own initiative to withdraw the references from the OJEU.	objects against the harmonised standard in question. Moreover, the Commission is not free to decide whether or not to withdraw the references to a harmonised standard from the OJEU. The Commission may only withdraw the references if the Committee on Standards has delivered an opinion favourable to such withdrawal or has delivered no opinion (examination procedure – in line with article 5 of Regulation 182/2011).	
4.2.4. Flowchart 1 Box at the bottom right of the image.	"Other specification than harmonised standards or direct application."		Please specify. Example: "Other specification than in the OJEU cited harmonised Standards..."
4.2.4 Legend to Flowchart 2, 3	"Adoption and notification of a standardisation request: The Commission adopts a request as a Commission..."	"notification" is a misleading term her. During the preparation of the Draft standardization request it is also notified to the public by announcing it in the notification system. This official step is carried in parallel to the ISC.	Find another term for "notification"
4.2.4 Legend to Flowchart 2, 7	"Article 4(3) of Regulation (EU) No 1025/2012 provides a procedure if a national standardisation body receives comments	Article 4 (3) only asks the NSB to "consult the European standardisation organisations and the Commission before adopting" the draft standard.	Please delete the sentence.

	indicating a possible negative impact on the single market"		
4.2.4 Legend to Flowchart 2, 9		The Formal Vote may be skipped.	Please add: Under specific conditions, the Formal Vote may be skipped, thus optimising the development time of the standard.
4.2.4 Legend to Flowchart 2, 12	"During these assessments it is examined in particular whether the draft or adopted harmonised standard is covered by the relevant standardisation request and whether essential or other legal requirements "aimed to be covered" are clearly indicated and covered by the standard. This assessment is not part of the internal standards setting and consensus building processes within the ESOs, which are private processes (see Point 4.2.5)."	The assessment aims at evaluating whether the standards fulfils/complies with the standardisation request and relevant legislation. It is part of the standardization process and de facto done by external consultants.	During these assessments it is examined in particular whether the draft or adopted candidate harmonised standard fulfils/complies with the requirements in the request and in relevant legislation. Despite the internal standards setting and consensus building process within the ESO which are private processes, this assessment, carried out by external consultants, has been integrated in the process (see Point 4.2.5).
4.2.4	"Verification of the	The original wording is much clearer and	Verification of the conditions for publication in the OJEU: According to Article 10(5) of

Legend to Flowchart 2, 13	conditions for publication in the OJEU: After receiving relevant references of harmonised standards from a ESO the Commission services need to verify that the assessment of compliance was done and its results"	should be kept.	Regulation (EU) No 1025/2012 the Commission has to verify whether the relevant harmonised standard complies with the initial request
4.2.4 Legend to Flowchart 12(3)/14	"(...) must publish the references of a harmonised standard in the OJEU (...)"		"(...) must publish the references of a harmonised standard **without any delay** in the OJEU (...)"
4.2.4 14.	"A presumption of conformity is usually valid from the date the publication is done in the OJEU and ends most commonly after a revised version of that harmonised standard is referenced in the OJEU. National transposition: National standardisation bodies		Please substitute "A presumption of conformity is usually valid from the date the publication is done in the OJEU and ends most commonly after a revised version of that harmonised standard is referenced in the OJEU but **usually granting a certain transition period**. National transposition: National standardisation bodies are obliged to transpose the relevant European standard[3] as an identical national standard on the basis of the internal rules of the ESOs. According to Article 3(6) of Regulation (EU) No 1025/2012 they also are obliged to withdraw any national standards which are conflicting with a harmonised standard **within a reasonable deadline as instructed by the ESOs**.

3 The transposition of the standard is a matter for the ESOs' rules. It is usually carried out before the references of the harmonised standard are published in the OJEU. However national transposition is not a precondition to get a presumption of conformity. In practise harmonised standards are usually available as transposed nationally standards while the list of harmonised standards published in the OJEU and relevant Union harmonisation legislation make direct reference to original European standards.

	are obliged to transpose the relevant European standard as an identical national standard on the basis of the internal rules of the ESOs. According to Article 3(6) of Regulation (EU) No 1025/2012 they also are obliged to withdraw any national standards which are conflicting with a harmonised standard."		
4.2.4 Legend to Flowchart 15	"Publication in the OJEU is challenged"	Original wording is much clearer and should be kept.	Please replace by: "Formal objection:"
4.2.4 15.	"Additionally the Commission may afterwards amend, at its own initiative, its previous Decisions and remove a reference of a harmonised standard from the OJEU on the basis Article 10(6) of Regulation (EU) No 1025/2012 "	Article 10(6) doesn't give such power of unilateral un-listing harmonised standard to the European Commission. The only ways to un-list is either normal update of the state of the art with new standard as agreed with the ESOs (as explained in point 14) or formal objection (Article 11) for which European Commission is not the initiator.	Please delete.
4.2.5 2nd paragra	"However, the presumption of	The sentence is inaccurate as some acts provide presumption of conformity based	Please add "except for some acts which provides presumption of conformity in case of absence of European standards directly based on international standards referenced in

ph	conformity is ensured only when applying the European version because of possible technical modifications introduced in it.	on national or international standards.	the Official Journal (e.g. LVD 2014/35/EU Article 13) or national standards (e.g. LVD 2014/35/EU Article 14).
4.2.5 2nd paragraph	Additionally ISO and IEC versions do not always contain information on relevant essential requirements supported by a standard.	ISO and IEC versions never contain this information on relevant essential requirements. Annex Z is a European Annex.	Please change into: Additionally ISO and IEC versions do not contain information on relevant essential requirements supported by a standard, which are instead included in the European standard adopting the international one.
4.2.5 7th paragraph	Examples of other reasons for non-publication of references in the OJEU include: ... the standard contains normative references to other specifications which are not acceptable because of their origin or lack of proper consensus building process during their adoption, or normative references which are not yet accessible, or undated normative references;...	The Commission confirmed that undated references are possible if duly justified by the TC.	Please change into: Examples of other reasons for non-publication of references in the OJEU include: ... the standard contains normative references to other specifications which are not acceptable because of their origin or lack of proper consensus building process during their adoption, or normative references which are not yet accessible, or non-justified undated normative references;...

4.2.5 Before last paragraph	The presumption of conformity that harmonised standards confer is in principle rebuttable, as the market surveillance provisions of Union harmonisation legislation foresee that measures may be taken against a product presenting a risk, where the non-compliance of the product is due to shortcomings in the harmonised standards conferring presumption of conformity, in which case the objection procedure (see section 4.2.7 below) shall be launched.	Already covered in section 4.2.6.	Please delete.
4.2.6 Heading	Procedures to challenge a harmonised standard	The presumption of conformity is challenged, not the harmonised standard.	Procedures to challenge the presumption of conformity of a harmonised standard.
4.2.6	The procedures to challenge a harmonised standard, by a Member State or the European	The presumption of conformity is challenged, not the harmonized standard.	Please change into: The procedures to challenge the presumption of conformity a harmonised standard, by a Member State or the European Parliament on the basis of Article 11(1) of Regulation 1025/2012 or by the Commission on the basis of Article 10(6) and their outcome do not affect its existence as a European standard as only European standardisation

	Parliament on the basis of Article 11(1) or by the Commission on the basis of Article 10(6) and their outcome do not affect its existence as a European standard as only European standardisation organisations can make decisions on the revision or withdrawal of their deliverables.		organisations can make decisions on the revision or withdrawal of their deliverables.
4.2.6	In the last case (prevention), it means that the standard will not become a harmonised standard and thus will not give any presumption of conformity at all.	In accordance with the definition of 1025/2012 the standard is already harmonized when being adopted. Only presumption of conformity is affected.	Please change into: In the last case (prevention), it means that the standard will not give any presumption of conformity at all.
4.2.6.1 3rd para	"Under Article 11(1) of Regulation (EU) No 1025/2012 a harmonised standard can be challenged at any moment after its adoption by CEN, Cenelec or ETSI as a European standard. The purpose of Article	Only the presumption of conformity is challenged, not the harmonised standard as such.	Please change into: Under Article 11(1) of Regulation (EU) No 1025/2012 presumption of conformity of a harmonised standard can be challenged at any moment after its adoption by CEN, Cenelec or ETSI as a European standard. The purpose of Article 11 (1) should be understood as providing a procedure to challenge the presumption of conformity in the context of definitions given in Article 2 of Regulation (EU) No 1025/2012.

	11 (1) should be understood as providing a procedure to challenge valid harmonised standards, i.e. not withdrawn harmonised standards or draft harmonised standards which cannot be regarded as adopted European standards in the context of definitions given in Article 2 of Regulation (EU) No 1025/2012. “		
4.2.6.2 1st paragraph	“As part of its responsibilities and duties according to Article 10(6) of Regulation (EU) No 1025/2012 and the relevant sectoral legislation, the Commission may, at its own initiative, adopt Commission Implementing Decisions to withdraw references of harmonised standards from the OJEU or	This is extrapolation, which is not as is in the law. Cases as described below are a shared responsibility with the ESOs, except in case of formal objection where it is member state or parliament, but never the own and single initiative of the European Commission. Article 10(6) does not mention anything like this. On the contrary, this article obliges the Commission to publish references of harmonised standards satisfying the requirements in the OJEU without delay. In accordance with the definition of 1025/2012, a standard is harmonized	Please delete.

	publish restrictions after initial publication of a reference."	when listed in the OJEU. Only the presumption of conformity may be challenged, not the standard as such.	
4.2.6.2. 3rd paragraph	Withdrawal of references from OJ by the Commission could be relevant in particular where the relevant edition of a harmonised standard is not anymore reviewed or updated by the ESO itself and where the ESO itself does not regard it as a standard (obsolete standards). Such cases include: the harmonised standard in question has been withdrawn by the relevant ESO without any intention to adopt a revised harmonised standard; the national standards transposing the harmonised standard are not available or valid as national standards anymore.	Standards undergo periodical review. There are no obsolete standards, especially harmonised standards. As long as an EN is valid national standards adopting this EN are valid and available.	Withdrawal of references from OJ by the Commission could be relevant in particular where the relevant edition of a harmonised standard has been withdrawn by the ESO itself or where the revised edition of a candidate harmonised standard has not been approved for citation in the OJ by the Commission.
4.2.6.2		This is extrapolation, which is not as is in the law. Cases as described below are a	Please delete.

		shared responsibility with the ESOs, except in case of formal objection where it is member state or parliament, but never the own and single initiative of the European Commission. Before deciding (by an implementing decision) to cite a standard in the OJEU the Commission shall verify whether the standard complies with the essential requirements as stated in Annex Z. Thus there is no need for such retrospective action.	
4.2.7 2nd paragraph		The former text was more precise and accurate.	Please restore former text. Please use after a formal objection" instead of "after a harmonised standard was challenged"
4.2.7 5th paragraph	"It is the Commission's responsibility to decide on dates when the references of revised harmonised standards are published in the OJEU and when the references of superseded harmonised standards are withdrawn from the OJEU."	This is inaccurate. Article 10(6) requests the EC to publish without delay.	Please change into: If a harmonised standard satisfies the requirements it aims to cover the Commission publishes the reference of this harmonised standard without delay in the OJEU and decides when the reference of the superseded harmonised standard is withdrawn from the OJEU.
4.2.6 6th paragraph	"Given that harmonised standards are part of EU law"	This is challenged, e.g. by the legal opinion of the German Federal Ministry for Economic Affairs and Energy.	Please change into: Given that harmonized standards are tools to demonstrate compliance with specific union law, it is ...
4.2.7	Because of the nature	The Commission confirmed that undated	Please change into:

Last paragraph	of harmonised standards, undated references to other standards where relevant clauses aim to support essential or other legal requirements should not be.	references are possible if duly justified by the TC.	Because of the nature of harmonised standards, undated references to other standards where relevant clauses aim to support essential or other legal requirements should be justified.
4.2.8 2nd paragraph	Some product legislation identify 'technical specifications' (or 'common technical specifications') as an alternative or a complement to harmonised standards...	The recourse to alternative common technical specifications, drafted by the EC, should be very limited and exceptional, because they do not guarantee the same level of stakeholders' participation, openness, transparency as the harmonised standards. ESOs can rely on a unique network of expertise throughout Europe and can deliver standards developed according to the principles of openness, transparency and consensus, providing to the Commission an added-value that is hard to match. It would be a step down to look for alterative or complementary technical specifications simply because ESOs and the Commission fail to find an understanding on a standardization request. Moreover, also Art 3 p 2 of the NLF decision (DECISION No 768/2008/EC) suggests that the Commission "shall" provide for the recourse to harmonised standards. Where Community harmonisation legislation sets	Please change into: In limited and exceptional cases, product legislation may identify 'technical specifications (or 'common technical specifications') as an alternative or a complement to harmonised standards ...

		out essential requirements. Hence the possibility to us technical specifications as alternative in these cases is limited, thus technical specification can only be used as a complement.	
4.2.8. Box, 1. bullet	"The conformity of a product may be demonstrated not only by harmonised standards but also by other technical specifications. This is essential because harmonised standards do not even cover all possible products or, in some cases, certain essential requirements. "	This statement is incorrect. There are numerous standards that actually cover all relevant products and requirements.	Correct sentence to read: "harmonised standards do not always cover all products or, in some cases, certain essential requirements"
4.3.2. 2nd paragraph 2nd sentence	"Furthermore, products within the scope of application of article 4 of Regulation 2019/1020 must also indicate the name and address of the economic operator established in the EU responsible for those products. "	This wording suggests that the economic operator under Regulation 2019/1020/EU would be persons other than manufacturers and importers!	Correct wording by deleting "Furthermore" and "also".
4.3.2.1	„ The manufacturers must indicate ....name	Section 4.3.2.1 describes rules for "requirement to indicate name and address	We suggest changing the text, i.e. adding a second sentence and expanding the (now) 6th sentence in the second paragraph of 4.3.2.1 and adding a new sentence afterwards

	and address must, as a rule, be affixed to the product. However, it may exceptionally be moved from the product if this rule cannot be followed.... In such cases the order of priority is that as a first alternative the information should be on the packaging, as a second alternative on an accompanying document [...]“	for manufacturers”. It also highlights “However, it may exceptionally be moved from the product if this rule cannot be followed.” It also reflects “It is up to the manufacturer to make this assessment.” A further precision would help manufacturers and Market Surveillance authorities for products that have space for some but not for all required elements (e.g. a EU contact address), especially because manufacturer have to consider markings/labeling from other EU regulations (CLP, WEEE...) too. I.e. for products / supplies that are supported only inside a product from the same manufacturer. It could even be an advantage to have some of these elements (like contact address) on packaging (during sales) and after installation the contact address is typically found anyway on the host product.	in addition: (black text = current text, red text = change proposal) The name and address must, as a rule, be affixed to the product. This requirement is to enable traceability. However, it may exceptionally be moved from the product if this rule cannot be followed. This would be justified where affixing it to the product was not possible under reasonable technical or economic conditions excluding however esthetical reasons. It is up to the manufacturer to make this assessment. This assessment has to be done according to the size or nature of the product and may take into requirements of other legislation to provide information. A relevant consideration relating to the nature of the product is where the product can exclusively be used with or within another product from the same manufacturer that already bears the manufacturer’s address. Some products e.g. hearing aids, sensors or the like are simply too small to carry such information. In such cases the order of priority is that as a first alternative the information should be on the packaging, as a second alternative on an accompanying document, except for the cases where sectoral Union harmonisation legislation requires the information to be on both the packaging and accompanying documents.
Para.2, 2nd and 6th sentences	"This would be justified where affixing it to the product was not possible under reasonable technical or economic conditions excluding however esthetical reasons. It is up to the manufacturer to make this	There is no legal basis for these statements. There is no indication of acceptable reasons for justifying the possibility of affixing the information on the product, or of the alleged "order of priority".	These statements should either be deleted or re-formulated as guidance or recommendation.

	assessment. This assessment has to be done according to the size or nature of the product. Some products e.g. hearing aids, sensors or the like are simply too small to carry such information. In such cases the order of priority is that as a first alternative the information should be on the packaging, as a second alternative on an accompanying document, except for the cases where sectoral Union harmonisation legislation requires the information to be on both the packaging and accompanying documents."		
4.3.2.1 4.3.2.3	"Nevertheless, it is useful to include also an email address and/or a phone number in the single contact point to facilitate swift contacts	There is no such requirement mentioned in the law.	We suggest deleting.

	with the relevant authorities."		
4.3.2	There is no explicit obligation that the addresses have to be preceded by the words "Manufactured by", "Imported by" or "Represented by" or "Fulfilled by".	While this states there is no explicit obligation, by calling it out in the prose, it suggests the responsibility for product safety/traceability. This should be deleted if Fulfilled By does not help address the safety concern.	There is no explicit obligation that the addresses have to be preceded by the words "Manufactured by", "Imported by" or "Represented by".
4.5	The EU declaration of conformity must be continuously updated. The EU declaration of conformity is specific to each individual product, even if they are manufactured in series.	Unclear what Continuously means. The wording of this sentence is misleading as it could imply that the DoC would need to undergo permanent changes. However, as correctly stated in the following sentences, the declaration has to be updated when changes occur in the legislation, the standards etc.	Please delete the first sentence. Correct wording of sentence to read: "The EU declaration of conformity must be kept up-to-date."
4.5 Para.6 5th bullet:	"(...) this implies that the version and/or date of the relevant standard is specified and whether it has been fully applied."	There is no legal basis for this requirement to indicate the full or partial application of a standard in the EU declaration of conformity. Rather, indication of the application, including the extent of the application, of a standard is provided in the technical documentation!	Delete the additional wording "and whether it has been fully applied".
4.6.1.4	However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the	Real estate on the product may require certain other markings take precedence – this sentence may create a practical challenge if the product is available in multiple jurisdictions which have similar marking requirements.	

	packaging, if any, and/or to the accompanying documents. In such a case, it is expected that no other marking of similar size is present on the equipment. The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant Union harmonisation acts.		
4.6.1.4 1st paragraph (2nd line)	"Stickers and other removable options would not respect the indelibility requirement"	If the stickers are complying with the standard requirements, it should be allowed.	We suggest deleting this statement, as it is contradicting other part of the Blue Guide. "It must also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards provide for a rub test with water and petroleum spirits)."
4.6.1.4	The requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. The CE marking should not be	The red texts are challenging for components having CE marking. Components are not visible in most finished products.	The red text shall be deleted or an additional clause on CE marking of components should be formulated.

	concealed and require manipulation of the product. The requirement for visibility does not necessarily mean that the CE marking must be visible before opening a products' packaging because affixing the CE marking also to the packaging is only necessary in case this is explicitly required in the relevant Union acts. For products requiring assembly, the CE marking should remain visible after assembly.		
4.6.1.4	The requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. The CE marking should not be concealed and require manipulation of the product.	What about if the product itself must be manipulated in order to use, i.e., laptop which one must lift the screen to use, could the mark be shown upon lifting the screen? This requires clarification.	

4.6.1.4 2nd paragraph	“The CE marking should not be concealed and require manipulation of the product.”	As long as the end user would see the CE mark during normal operation of the product (without use of tools), it can be placed anywhere on the apparatus.	We suggest deleting the statement and replace with: “The CE marking may be placed anywhere on the apparatus as long as no tool is needed to access and view the marking.”
4.6.1.4 Paragraph 6 (last sentence of the paragraph)	“However, electronic labelling only is not allowed”	The sentence has been seen as one of the obstacles for e-labelling for a long time. Indicating the CE marking and any required warnings, information and labels according to applicable legislation is not required by any NLF directive and has no legal basis. A guidance document doesn’t have purpose of adding new requirement. In addition, this is not consistent with other kind of shop, e.g. in conventional shop, if product is in a sealed box, the end-user won't have access to such document before buying the box; such requirement doesn't apply to paper catalogue. This is not consistent with the principle that e-labelling is not accepted in the EU.	We suggest deleting this sentence.
4.6.1.4 Para. 2 4th sentence	"For products requiring assembly, the CE marking should remain visible after assembly ."	Statement seems unclear and impracticable. For products which are intended for assembly/integration into other products and which are themselves CE-marked it should be sufficient that the CE marking (and other mandatory markings if applicable) is visible and accessible only before the final assembly and can become visible after disassembly (e.g. mounting of	Delete the proposed sentence and replace it as follows: "For (finished) products which are intended for assembly/integration into other products and which are themselves CE-marked, it is sufficient that the CE marking (and other mandatory markings if applicable) is visible and accessible before the final assembly and can become visible after disassembly."

		top-hat rails in control cabinets). There is no legal basis for a requirement such as suggested by this new sentence, and it would in most cases be impossible to fulfil it. Products covered by legislation requiring CE marking bear the CE marking according to that legislation in a visible and permanent form. If such products are incorporated as components into a complete product by a subsequent manufacturer it is in most cases necessary that these incorporated components are covered by the housings or enclosures which cannot be easily removed for functional and safety reasons (e.g. electric motor or switching devices inside a washing machine, safety components inside a machine,...). Similar conditions exist in industrial and building installations: electrical installation devices are to be assembled in an inaccessible manner into installation boxes or are mounted invisibly into walls or other building structures. Installations for chemical industry often need also enclosures or thermal insulation which makes installed equipment invisible.	
4.6.1.4 Para. 6, last sentence	"Regulation (EC) 765/2008 and Decision 768/2008/EC lay down that the CE marking must have the	The "affixing" should be interpreted to keep pace with technological developments in the respective product areas. Digitalization offers a variety of new possibilities to mark products with relevant	Amend sentence to read: "Electronic labelling may be used for the affixing of CE marking, provided it is affixed visibly, legibly and indelibly."

	dimensions, format and proportions defined in Annex II of Regulation (EC) No 765/2008 and be legible and clearly affixed. Regulation (EC) 765/2008 and Decision No 768/2008/EC do not forbid any kind of design (e.g. “hollow” design) as long as the above conditions are respected. However, electronic labelling only is not allowed."	required information, which both ensure compliance with regulatory aspects (e.g. indelible, legible, visible) and provide additional elements for the benefit of users and authorities alike. Electronic labelling is an advanced technology that is accepted by a number of countries today and even under some Union harmonisation legislation (e.g. the wheel mark). It should also be accepted for the purpose of CE marking (as an option).	
4.6.1.4 Para. 7	In addition, if products are sold online, the CE marking and any required warnings, information and labels according to applicable legislation shall be indicated in that website ; these items shall be clearly visible in its entirety before the consumer is carrying out the purchase.	We strongly oppose these statements. There is no legal basis for this requirement ("shall", although the Blue Guide is only guidance). Also, its implementation would imply substantial additional cost and expenditure for the generation and continuous update of the relevant websites and for the information to be included. Besides, it is established that consumers do not normally require such information when purchasing products in the shops (not online).	To be deleted.
5.2.2. Para. 13	"Concerning the subsidiaries and	The issue of "related bodies" and the question of how to handle this with regard	The sentence should be deleted.

	subcontractors of a notified body, a notified body may have a conflict of interest and cannot perform conformity assessment on items where e.g. a related (to the notified body) company (i.e. subsidiary or subcontractor) has been involved with the manufacturer by means of consultancy or has participated directly or indirectly in the in the design, manufacturing, installation etc. of the product or type of product. To avoid such a conflict of interests the notified body should identify the risks coming from e.g. the subsidiaries/subcontractors companies or persons offering those services, make this information available and state that if these	to the requirement for independence of the notified body is very specific and always depends on the individual case/situation. Union harmonisation legislation limits itself to setting out only the essential requirements in terms of objectives to be reached. Similarly, for notified bodies and their competencies, it should be left to harmonised standards, drawn up by the experts on the matter, to provide further details as to the application and implementation of these requirements. Legislation should not interfere with the dynamics of the state of the art in the area of conformity assessment.	

	companies provided services to a manufacturer for a specific product the notified body is unable to provide conformity assessment to that manufacturer for the concerned items."		
5.2.3 Last paragraph	“However, accepting the results of the manufacturer’s tests is not as such sufficient to fulfil its tasks as notified bodies and additional tests will have to be performed under the applicable module by the Notified Body.”	This text is too strict, as in most cases the results of the manufacturer’s tests will be sufficient and can be accepted.	We suggest using the word ‘may’ (2x). “However, accepting the results of the manufacturer’s tests **may** not **be** as such sufficient to fulfil its tasks as notified bodies and additional tests **may** have to be performed under the applicable module by the Notified Body.”
5.2.3 Para.2	"Some sectoral legislation provides for an EU-type examination when harmonised standards do not exist or are not applied by the manufacturers. Consequently, in order to ensure a correct implementation of the internal market rules,	Sentence should be formulated more clearly. The "expectation" stated is actually a requirement which notified bodies must fulfil and which needs to be assessed during the application for notification of the candidate body.	Clarify sentence to read: "Some sectoral legislation provides for the application of a conformity assessment module that provides for the mandatory involvement of a notified body (e.g. EU-type examination) in cases where harmonised standards do not exist or are not applied by the manufacturer. Consequently, in order to ensure a correct implementation of the internal market rules, Notified Bodies are required to be able to demonstrate that they have the competences to perform the required conformity assessment and to issue the required attestation to certify that the regulatory requirements have been fulfilled, also in the (complete) absence of harmonised standards."

	Notified Bodies are expected to have sufficient competences to run an EU-type examination in the complete absence of harmonised standards."		
5.2.4 3rd paragraph	"Where cases relating to harmonised standards are discussed, with significant doubts on the presumption of conformity, the group of the Notified Body is expected to inform the Commission and the Member States."	The guide should not add requirements that are not requested in the relevant legislation. In addition, Notified Bodies and their groups can provide input directly to the ESOs during the normal drafting processes.	Remove or change as below: "Where cases relating to harmonised standards are discussed, with significant doubts on the presumption of conformity, the group of the Notified Body **can** inform t**he relevant ESO via the typical standardisation process**"
7.1 6th paragraph	"Member States should allow for sanctions proportional to any infringements. These should also act as a powerful deterrent"	This should be done only in in case of repeated and serious infringements.	Member States should allow for sanctions proportional to any infringements. These should also act as a powerful deterrent **in case of repeated and serious infringements.**
7.2	Member States must ensure effective surveillance of their market. They are required to organise and carry out the monitoring of the	Does this imply that monitoring is occurring online for marking and documentation? i.e., must such information be available at the point of sale that is consistent with what an authority may find at a brick and mortar (inspect the entire packaging and any other	

	products made available on their market or imported through both online and offline sales and distribution channels. This is in order to ensure that products have been designed and manufactured in accordance with the Union harmonisation legislation requirements, that the marking and documentation requirements have been respected, and that they have been subjected to the necessary procedures.	available information? Examples and better clarification should be provided.	
7.2 5th paragraph	"A provision in Union harmonisation legislation should be considered 'specific', and thereby render the corresponding provision of the Regulation (EU) 2019/1020 inapplicable, when it offers an equivalent	That opens the door for misinterpretation and misuse, because "lex specialis" means more specific, not higher level.	We suggest deleting this sentence.

	solution guaranteeing the same level (or a higher level) of protection as their corresponding counterpart in Regulation (EU) 2019/1020."		
7.3.1 6th paragraph	As the Regulation refers to the totality of the costs of the activities of market surveillance authorities with respect to instances of non-compliance, the type of costs that can be reclaimed is broad and not limited to the examples given in Article 15(2).	Art. 15 (2) says "may", so it can be read that it is not limited to the costs listed in that Article. However, we should try to limit the totally of costs as much as possible.	Please delete.
7.3.3	Considering that the aim of market surveillance is to provide a high level of protection of certain public interests, informing the public is an essential element of market surveillance. Therefore (...)	It should be added that sufficient information should be provided so that the public and businesses can identify if their product is affected by a safety issue, e.g., set a minimum standard for Recall notifications.	

7.4.1 9th paragraph	"If common campaigns are organised for a specific sector, Market Surveillance Authorities are also expected to provide a feedback on the state-of-the-art in that sector, so to allow the ESOs and the Notified Bodies to assess, respectively, whether the harmonised standards and the certificates sufficiently mitigate the risks in the light of the available technology."	This is usually done by formal objection.	Please adjust paragraph.
7.4.2.1 1st paragraph	"Market surveillance authorities must first contact the relevant economic operator informing it about the finding and giving an opportunity to provide its view within a reasonable timeframe. period of 10 working days"	It should be up to each member state to determine the deadline for replies, not to the European Commission. There is no legal background for 10 days.	We suggest deleting this sentence.
7.4.2.1	The next step is to require the relevant economic operator to	This does not follow the prior step. The information requested in the prior step must be evaluated and integrated into a	

	take appropriate and proportionate corrective action to bring the non-compliance to an end or to eliminate the risk. The market surveillance authorities must also inform the relevant notified body (if any).	risk assessment to determine if a corrective action is necessary and what action should be taken. Triggering product suppression or recall otherwise will damage business and consumer trust.	
7.4.2.1	If there is a manufacturer or importer in the EU, the market surveillance authority should address them directly, unless the issue specifically relates to a distributor or another economic operator. If the manufacturer is based outside the EU, the market surveillance authority should contact its authorised representative if such exists or attempt to contact the manufacturer in the third country. For certain categories of	This needs to be clearly defined in the context of “no other Economic Operator in the EU” per the Goods Package.	

	products they also have the option of contacting the fulfilment service provider in the EU.		
7.4.2.2 4th paragraph	"Examples of typically formal non-compliance could also be the situations where other conformity markings provided for in the Union harmonisation legislation are incorrectly affixed, or where the EU declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory, or the requirement to accompany other information provided for in sectoral Union harmonisation legislation is complied with insufficiently, or, where applicable, the identification number of the notified body	A typical formal non-compliance is also missing manufacturer or importer name and address, why we suggest adding it here.	Examples of typically formal non-compliance could also be the situations where other conformity markings provided for in the Union harmonisation legislation are incorrectly affixed, or where the EU declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory, or the requirement to accompany other information provided for in sectoral Union harmonisation legislation is complied with insufficiently, or, where applicable, the identification number of the notified body has not been affixed to the CE marking, **or where the manufacturer or the importer has not affixed his name and address to the product or the accompanying documents.**

	has not been affixed to the CE marking."		
7.6.1	When a market surveillance authority decides that a product is non-compliant it is considered non-compliant throughout the EU.	This needs to have clear context. If it is non-compliant for a specific issue, such as language, then there is no reason for it to be considered non-compliant throughout the EU.	
10.2		R&TTE is still mentioned	Update with 2014/53/EU
10.3			Suggest adding the link to NANDO website.
10.3		The Commission's 'supplementary guidance on the LVD/EMCD/RED' is missing.	Add: https://ec.europa.eu/docsroom/documents/29121/attachments/1/translations/en/renditions/native