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

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

GUIDANCE DOCUMENT ON THE PPE TRANSITION FROM DIRECTIVE 89/686/EEC TO REGULATION (EU) 2016/425

The new **PPE Regulation (EU) 2016/425**[1] is the result of the alignment of the previous PPE Directive 89/686/EEC to the "New Legislative Framework" (NLF)[2], in particular to Decision No 768/2008/EC[3], as well as to the provisions of the Treaty on the Functioning of the European Union (TFEU) after the Treaty of Lisbon.

Even if the PPE Directive 89/686/EEC has been substantially successful in achieving the intended goals, a broad consensus existed on the need for some improvements. The main changes in Regulation (EU) 2016/425 are the following:

- *Legal instrument*: a Regulation, directly applicable, instead of a Directive requiring national transposition acts
- *Scope*: enlarged to include PPE designed and manufactured for private use to protect against heat
- *Essential health and safety requirements*: the PPE must provide protection against "the risks against which it is intended to protect", no longer "against all risks encountered ". Other minor modifications
- *Risk categories*: only risk-based definitions and exclusive lists of risks, simplification
- *Conformity assessment procedures*: adapted to the modules of NLF
- *Definitions*: horizontal additions from the NLF
- *Economic operators* (manufacturers, authorised representatives, importers, distributors) *and their obligations*: more detailed descriptions from the NLF
- *Harmonised standards and presumption of conformity*: reference to Regulation (EU) No 1025/2012 on European Standardisation[4]

[1] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment (OJ L 81, 31.3.2016, p. 51)

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

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

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

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- *CE marking*: reference to Regulation (EC) No 765/2008[5]
- *Notified bodies*: more detailed requirements and procedures from the NLF
- *Market surveillance and safeguard procedure*: reinforced activities and new simplified procedures
- *PPE committee and implementing acts*: reference to Regulation (EU) No 182/2011[6] ("Comitology") concerning Commission Implementing Decisions on formal objections against harmonised standards, safeguard clauses against products and challenges on the competence of notified bodies
- *EU declaration of conformity*: more detailed contents, and a model, from the NLF
- *EU-type examination certificate*: conditions for validity and date of expiry from the NLF

The new PPE Regulation (EU) 2016/425 is applicable from **21 April 2018**, except the articles on notification of notified bodies, PPE committee and penalties which become applicable at different earlier stages.

This document includes a list of "Frequently Asked Questions and Answers" on the transition to the PPE Regulation (EU) 2016/425, which covers both "horizontal" and "sectorial" questions, this is to say, those common to all the EU legislation aligned to the "New Legislative Framework"[7] and those specifically related to Regulation (EU) 2016/425. It should be noted that this document is preliminary, pending the publication of the new PPE Guidelines. Upon finalisation of the PPE Guidelines (planned for the second half of 2017) this document has to be considered as the main references for the interpretation of the PPE Regulation. For horizontal issues, the reference document is the 'Blue Guide' on the implementation of EU product rules[8].

A list of reference documents for guidance is provided at the end of the document.

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and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12)

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

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

[7] *Pyrotechnic Articles* Directive 2013/29/EU (applicable 1 July 2015); *Civil Explosives* Directive 2014/28/EU, *Simple Pressure Vessels* Directive 2014/29/EU, *Electromagnetic Compatibility* Directive 2014/30/EU, *Non-automatic Weighing Instruments* Directive 2014/31/EU, *Measuring Instruments* Directive 2014/32/EU, *Lifts* Directive 2014/33/EU, *ATEX* Directive 2014/34/EU, *Low Voltage* Directive 2014/35/EU; *Radio Equipment* Directive 2014/53/EU; *Pressure Equipment* Directive 2014/68/EU; *Marine Equipment* Directive 2014/90/EU; *Cableway Installations* Regulation (EU) 2016/424; *Personal Protective Equipment* Regulation (EU) 2016/425 and *Gas Appliances* Regulation (EU) 2016/426. See http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

[8] http://ec.europa.eu/DocsRoom/documents/18027/

FREQUENTLY ASKED QUESTIONS AND ANSWERS ON THE TRANSITION TO THE PPE Regulation (EU) 2016/425

TOPIC	QUESTION	ANSWER
Scope ***Article 2***	Is there any change in the scope from Directive 89/686/CEC to Regulation (EU) 2016/425?	Yes. When compared with the previous Directive 89/686/EEC, the scope of Regulation (EU) 2016/425 includes equipment designed and manufactured for private use to protect against heat. The relevant exclusion in the Directive has been removed.
Applicability	Is the Regulation applicable only to EU Member States?	The Regulation is a text with EEA relevance, i.e. Liechtenstein, Iceland and Norway, which are part of the EEA, have to be considered in the same way as EU Member States. This means that whenever a new EEA-relevant legal act is adopted by the EU, a corresponding amendment should be made to the relevant Annex of the EEA Agreement. This is essential in maintaining the principle of homogeneity of the EEA and ensures that the text is as close as possible to the adopted legislation on the EU side, with a view to permitting a simultaneous application in the Community and in the EEA EFTA States. In addition, countries where the "acquis communautaire" applies thanks to specific agreements (e.g. Switzerland, Turkey) are required to apply the Regulation in their territories.
Manufacturer ***Article 3(4) and recital 23***	Who is a manufacturer – can an operator/user also be a manufacturer?	According to Article 3(4) of the PPE Regulation (EU) 2016/425, any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its own name or trademark, is a manufacturer. Users and operators can only be considered as manufacturer if they manufacture products and place them on the market under their name or trademark. Additionally, recital 23 clarifies the relationship with Directive 89/656/EEC on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace: manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements laid down in this Regulation. This means that an operator/user who produces a product for his own use (the use of its employees) becomes a manufacturer and must ensure that all the related

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		obligations and requirements of the Regulation, including the necessary conformity assessment procedures are met. *See also § 3.1. "Manufacturer" in the "Blue Guide"*
Other economic operators **Article 3 (8) and recital 9**	Can following operators be considered as "economic operators" similar to importers or distributors? - "Agent" which is a person inside the EU that promotes goods via a homepage or somewhere else and is paid when people order the goods and after requests the manufacturer outside the EU to send directly the batch of products or one single product to the customer - "Fulfilment houses" which put just the EU citizen address label and send the goods	"Economic operators" are defined in Article 3(8) of the PPE Regulation (EU) 2016/425 as "the manufacturer, the authorised representative, the importer and the distributor". The common element to all these actors is that they make products available on the market. New distribution modes (in particular in electronic commerce) have developed and there are new types of actors, like agents or fulfilment houses. Recital 9 makes clear that the Regulation should apply to all forms of supply, including distance selling. Therefore, the economic operators acting online are subject to the same obligations as traditional economic operators. *See also § 3. "The actors in the product supply chain and their obligations" in the "Blue Guide"*
Making available on the market / Placing on the market ***Article 3(2) and (3)*** ***Articles 7, 8, 9, 10***	Which is the difference between "making available on the market" and "placing on the market" in the framework of Regulation (EU) 2016/425 (e.g. in Article 7 "making available on the market" is mentioned, but for the same activity when the responsibilities of economic operators are covered – e.g. Articles 8, 9 and 10 – "placing on the market" is mentioned)?	"Making available on the market" is the overall concept. Any transfer between economic operators of a product is considered as making available. "Placing on the market" is a specific case of making available, namely it is the first time that the product is introduced on the market. It is important because at that moment the EU legislation applies. Any subsequent transfer is a "making available". The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, that operation is labelled in legal terms as placing on the market. Any subsequent operation, for instance, from a distributor to another or to an end-user is defined as making available. It should be noted the difference between "making available on the market" in Article 7, as the general concept referred to free movement in the EU internal

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		market in any moment, and "placing on the market" in Articles 8, 9 and 10, referred to the first time that the product is introduced on the EU market. As regards the case of products manufactured for the manufacturer's own use the product is not placed on the market: in this case the legislation applies at the moment of putting into service. *See also §§ 2.2. "Making available on the market" and 2.3. "Placing on the market" of the "Blue Guide"*
	Which kinds of obligations are related to selling products through the internet?	EU harmonisation legislation applies to all form of supply, including distance selling and selling through electronic means (as the internet): in any case, products intended to be made available on the EU market must be in conformity with the applicable legislation. A product offered in a catalogue or by means of electronic commerce has to comply with EU harmonisation legislation when the catalogue or website directs its offer to the EU market and includes an ordering and shipping system. Products offered for sale online by sellers based outside the EU are considered to be placed on the EU market if sales are specifically targeted at EU consumers or businesses. *See also § 2.1. "Product coverage" of the "Blue Guide"*
	In many cases products can be marketed through the internet or other distance/electronic means but the product is not physically in the EU. Placing on the market requires the products to be physically in the EU territory?	
Obligations of manufacturers: **Type, batch or serial number** ***Article 8(5)***	Does this Article mean that a product specification is required, but not necessarily a serial number? Would there be a way to specify the sequential serial number using a barcode?	The important point is that the numbering must allow making a clear link to the relevant documentation that demonstrates the conformity of the specific type of product, in particular for PPE the EU declaration of conformity or the attestation of conformity. A barcode can be used if this can reasonably be considered by a manufacturer as an appropriate way enabling the manufacturer and authorities to identify and trace his products and to make the link to the relevant documentation. Depending on the product, it is up to the manufacturer to decide whether the identification element should allow the identification of each single product or just the relevant batch or type. But manufacturers should be aware that when public authorities in charge of market surveillance recall products and it is not

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		possible to distinguish between batches or serial numbers, all products of that brand must be removed from the market. The PPE Regulation allows placing the information on the packaging or in a document accompanying the product if the size or nature of the product does not allow it. Of course if the information is not visible at a first sight, it must be easily and safely accessible. *See also § 4.2.2.3. "Identification element" of the "Blue Guide"*
Name and address on the product ***Article 8(6)***	In case of lack of space, would be possible to indicate the name and address within the product?	The manufacturer must indicate his (1) name, (2) registered trade name or trade mark and (3) a single contact postal address at which he can be contacted, on the product or, when not possible because of the size or physical characteristics of the product, on its packaging and/or on the accompanying documentation. If the information is put inside the product, it must be easily accessible by the Market Surveillance Authorities without damaging the product or the need for disassembling it with specific tools. *See also §§ 3.1. "Manufacturer" and 4.2.2.1. "The requirement to indicate name and address of the manufacturer" of the "Blue Guide"*
	Must the information refer to the local distributor or the economic operator placing the product on the EU market?	The information is related to the economic operator that places the product on the market i.e. the manufacturer and, if applicable, the importer, not the distributor.

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	In the case that a company is based in a third country and in an EU country, is it necessary to put the information of both places as manufacturer and importer?	For imported products, it is required to indicate the name and address of the manufacturer and of the importer, as a basic traceability requirement for market surveillance. But, if both, manufacturer and importer, belong to the same group or company and if the company based in the EU takes the full manufacturer's responsibility, the indication of the branch based in the EU will suffice to comply with the requirements. *See also § 4.2.2. "Traceability provisions" of the "Blue Guide"*
	The postal address in which the manufacturer can be contacted, must be the one of the manufacturer?	Not necessarily. The postal address must be "at which [the manufacturer] can be contacted": this is not necessarily the address where the manufacturer is actually established. This address can for example be the one of the authorised representative or of the customer services. *See also § 4.2.2.1. "The requirement to indicate name and address for manufacturers" of the "Blue Guide"*
	How to implement the requirement that the contact details shall be in a language easily understood?	The address does not have to be translated. The characters of the language must allow identifying the origin and the name of the company. This is not possible with certain alphabets.
	What elements are needed to constitute an address? Does it always need a street name, house no. etc.?	The address must be specific enough for a letter to arrive in the right place. Not all addresses are composed of street names and/or house numbers.
Instructions and safety information ***Article 8(7)***	What can be considered as manufacturer's documentation within the PPE Regulation?	The documents that are required to accompany the product include the instructions and information set out in point 1.4 of Annex II, to be drawn up and provided by the manufacturer to the end-user of the product. One single document can include both instructions and safety information. It must include also a copy of the EU declaration of conformity or contain in the instructions the internet address at which it can be accessed, as per Article 8(8).

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	Should each product sold in a bulk contain the instructions and safety information?	In principle, every individual product must be accompanied by the instructions and safety information. Whilst the safety information needs to be provided on paper, it is not required that the full instructions must be given in paper but they can also be on electronic or other data storage format. In some specific cases, where several identical products are bundled in a packaging (e.g. lab gloves), it is sufficient to accompany the shipping unit with one set of instructions. If another economic operator along the distribution chain dismantles the bundle and sells the products individually, he should ensure that each product individually sold is accompanied by the necessary instructions and safety information. *See also § 3.1. "Manufacturer" of the "Blue Guide"*
Provision of information and documentation ***Articles 8(10), 10(9) and 11(5)***	May "a competent national authority" in any Member State or EEA country contact an economical operator (manufacturer, importer, distributor) for information and documentation directly without any involvement of the local national authorities, or not?	The Regulation makes reference to "a competent national authority", that could be any of the countries of the EU and the EEA in which EU legislation applies. Any competent market surveillance authority can and is recommended to contact directly the economic operator even if it is based in a different Member State. The information of local national authorities in direct contacts between any national/EEA authority and economic operators, is advisable, for a matter of transparency and good co-operation. If the authority needs information to complete the compliance evaluation and the economic operators does not provide the information requested, then the first authority can request the assistance of the local national authority. The legal basis for this type of mutual assistance is set out in Article 24(2) of Regulation (EC) 765/2008. If the economic operator does not voluntary take corrective action, the competent national authority will adopt corrective measures concerning its country and notify them as appropriate via ICSMS/RAPEX Rapid Alert System. The market surveillance authorities of the other Member States will take follow up measures in the context of the safeguard clause procedure and in particular the local national authority will contact the manufacturer/EU importer and requests corrective action in relation to all relevant products. *See also §§ 7.4. "Member States responsibilities" and 7.5. "Cooperation*

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		between the Member States and the European Commission" of the "Blue Guide"
Contact details ***Recitals 13 and 17 Articles 8(6) and 10(3)***	Can manufacturers and importers use an e-mail address instead of a postal address?	Websites and e-mail addresses can be used **in addition to** the postal address.
Declaration of conformity (DoC) and manufacturer's instruction ***Recital 24, Articles 8(8), 9(2), 10(8), Annexes VI,VII,VIII, IX***	How shall the DoC accompany the product? Does the DoC need to include the serial/batch number?	The DoC can either physically accompany the product, or the internet address at which it can be accessed must be included in the manufacturer's instruction. In case the internet option is chosen, different solutions can be used (e.g. direct web address, generic webpage with search function), but it must be clearly explained how to obtain the DoC for the PPE via this route. The DoC needs to contain a number identifying the product. This number does not need to be unique to each product. It could refer to a product, batch, type or a serial number. This is left to the discretion of the manufacturer. *See also § 4.4. "EU Declaration of Conformity" of the "Blue Guide"*
Obligations of importers: **Ensuring the manufacturer's requirements** ***Article 10(2)***	How do we interpret "Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure… has been carried out by the manufacturer"? Does it mean that the importers must have a copy of the EU declaration of conformity or the attestation of conformity and the related technical documentation?	The importer needs to have a copy of the EU declaration of conformity and has to keep it for 10 years after a product has been placed on the market. The importer has to ensure that the technical documentation can be made available to the competent national authority upon request. Even if there is no explicit obligation, the importer is advised to require formal assurance in writing from the manufacturer that the documents will be made available when requested by the market surveillance authority. What is important is that the authorities receive the documentation and that at importer's request the manufacturer provides the information to Member States. The importer has to make sure that the manufacturer has carried out the appropriate conformity assessment procedure for the product. Therefore, the importer must check whether the manufacturer has fulfilled his requirements,

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		but it does not have to carry out a "new" conformity assessment of the product. In addition to that, the importers has a due diligence obligation with regard to the conformity of the product. If he has further information that should reasonably make him believe that the product is not in compliance he should not place the product on the market. The manufacturer retains the overall responsibility for compliance; such responsibility cannot be transferred to the importer. *See also § 3.3. "Importer" of the "Blue Guide"*
	What exactly are the "required documents" that are mentioned in this paragraph?	The "required documents" that the importer needs to make sure are present are the ones which have to accompany the product, as described in each EU legislation. In the PPE Regulation it is stipulated that the instructions and safety information must accompany the product, together with the EU declaration of conformity or the internet address at which it can be accessed.
Language of instructions and safety information ***Article 10(4)***	Can the product be imported with instructions only in English created by the manufacturer, and can the importer himself create a translation of the instructions that will accompany the product when is placed on the EU market?	The manufacturer, the importer and the distributor have the obligation to ensure that the product to be placed on the EU market is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State(s) concerned. It is for each economic operator which makes available the product in a Member State, to ensure that all the required languages are available. Nothing prevents economic operators from reaching contractual agreements on the manner in which they are translated.
	What happens if the product is placed on a national market for which the manufacturer has not foreseen a translation?	A manufacturer has a certain set of languages where he intends to ship the product but if it goes somewhere else, importer and distributor must ensure that instructions are translated in the required language(s). It depends on how economic operators are organised by contractual arrangements.
	What happens with "bad" translations?	According to Article 8(7), instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible. Therefore, "bad" (inaccurate, incomplete, etc.) translations cannot be accepted and the product

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		should be considered non-compliant.
Obligations of distributors ***Article 11(2)***	What exactly are the "required documents" that are mentioned in this paragraph?	The "required documents" that the distributor needs to make sure that are present are the ones which have to accompany the product, as described in each EU legislation. In the PPE Regulation it is stipulated that the instructions and safety information must accompany the product, together with the EU declaration of conformity or the internet address at which it can be accessed.
	How do the distributors check whether the requirements were met except for the CE marking and the instructions and safety information?	The distributor must not carry out any specific additional checks apart from those explicitly mentioned in Article 11. He also has to check that the manufacturer and importer have indicated their name, registered trade name or trade mark and the address at which they can be contacted on the product, or, when not possible because of the size or physical characteristics of the products, on its packaging and/or accompanying documentation, and that the product bears a type, batch or serial number or other element allowing its identification. The distributor must be able to identify the person (e.g. manufacturer or his authorised representative, the importer or another distributor) who has provided him with the product in order to assist the market surveillance authority in its efforts to obtain the EU declaration of conformity or the attestation of conformity and the necessary parts of the technical documentation. Market surveillance authorities have the possibility to address their request for the technical documentation directly to the distributor. The latter is, however, not expected to be in possession of the relevant documentation. In addition to that, the distributor also has a due diligence obligation with regard to the conformity of the product. If he has further information that should reasonably make him believe that the product is not in compliance he should not make the product available on the market. *See also section 3.4. "Distributor" of the "Blue Guide"*
Provision of	How long should it take for distributors to	There is not specific time limit in the Regulation for a "reasonable period".

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information and documentation ***Article 11(5)***	provide the necessary documents, taking into account the fact that even the smallest distributor should provide the information?	This period has to be assessed by the authorities on a case-by-case basis, taking into account the level of urgency/seriousness of risk and the efforts for the economic operator to follow-up the request.
Harmonised standards ***Article 14***	Are new lists of references of PPE harmonised standards to be published on the OJEU in the date of applicability of the new Regulation? What would happen if new harmonised standards are not published in such date?	The Commission is preparing a new standardisation request to replace the existing mandate for PPE (M/031). Article 46 of the PPE Regulation stipulates that "*References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex X*". The new standardisation request will require that a list of proposed harmonised standards is submitted by the European Standardization Organizations (ESOs) in due time so the Commission can assess the standards before citing them in the OJEU. The goal is to publish a list of references of PPE harmonised standards before 21st April 2018; when products are not covered by harmonised standards cited in the OJEU under the PPE Regulation, their conformity will need to be assessed directly to the essential health and safety requirements of the Regulation. Harmonised standards may or may not cover all applicable Essential Health and Safety Requirements (EHSRs); in the latter case the manufacturer has, in addition to the application of these standards, to assess the conformity to the EHSRs not covered by using other relevant technical specifications and test methods. Since the aim of the Regulation is that all the EHSRs applicable to the PPE are met, the Notified Body must verify that all the relevant applicable EHSRs to the PPE are met and referred to in the manufacturer's technical documentation (Annex III of the Regulation). *See also section 4.1.2. "Conformity with the essential requirements:*

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		harmonised standards" of the "Blue Guide"
EU declaration of conformity ***Article 15***	From which date a manufacturer has to mention the new PPE Regulation for his EU declaration of conformity?	Before 21 April 2018 all the EC declarations of conformity for PPE products placed on the EU market for the first time must be in line with Directive 89/686/EEC. PPE placed on the EU market during the transitional period (21 April 2018 to 20 April 2019) can either be accompanied by a declaration of conformity to Directive 89/686/EEC or by a declaration of conformity to the new Regulation (if all the requirements of the Regulation are complied with). According to Article 47 products that are already in the distribution chain before 21 April 2019 can continue to be made available with the EC declaration of conformity referring to Directive 89/686/EEC, as they have already been lawfully placed on the EU market. Declarations of conformity (EC or EU) remain valid according to the legislation in force when the product is placed on the EU market (= made available on the EU market for the first time). There is no need to change legislative references in documents accompanying the product. For products placed on the EU market as of 21 April 2019, the EU declaration of conformity must be in accordance with the new PPE Regulation (EU) 2016/425. Please note that placing on the market always refers to the single item, not to a series or to a type of product.
	How old a declaration of conformity can be, when placing a product on the market?	The EU declaration of conformity shall demonstrate the fulfilment of the applicable essential health and safety requirements set out in Annex II at the time a product is placed on the market, and shall identify the PPE for which it has been drawn up. If there have not been any changes in the design and production of the PPE and no changes in the state of the art (as from the harmonised standards, if available) took place, the same declaration of conformity can continue to be used.
	Is it necessary to change the declaration of	It would depend on the kind of changes in the new harmonised standard

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	conformity when the referred harmonised standards change?	superseding the previous one, as indicated by the relevant European Standardisation Organisation (CEN, CENELEC) in the standard itself. For "substantial" changes, related to the state of the art, re-assessment of the product will be necessary; for "formal" or "non-substantial" changes, an update of the declaration of conformity will be enough. The important issue to consider is that the previous standard has lost the presumption of conformity, so conformity is no longer "presumed" but has to be demonstrated, in particular in the technical documentation.
Structure and contents of the EU declaration of conformity ***Article 15(2)***	Which information must be included in the EU declaration of conformity?	If a manufacturer produces an EU declaration of conformity that follows strictly the model set out in Annex IX to Regulation (EU) 2016/425, as a minimum, he will completely fulfil the requirements of the EU declaration of conformity. The elements specified in Annexes IV, VI, VII and VIII do not add any additional requirement. In any case, additional information can be included.
	Annex IX requires "References to the relevant harmonised standards used" when other EU legislation (for instance Directive 2014/30/EU, Annex IV) require "References to the relevant harmonized standards used, *including the date of the standard*". Does it mean that for the PPE Regulation it is not mandatory to mention the date of the standards used?	The reference of the harmonised standard should be indicated in a precise, complete and clearly defined way; this implies that the version and/or date of the relevant standard should be specified. Therefore, it can be necessary to include the date if the version cannot be identified in a different manner (e.g. year of adoption). This is especially useful when two versions of the same standard are providing for presumption of conformity at the same time, during the transitional period between the publication of the reference of the superseding standard on the OJEU and the date of cessation of presumption of conformity of the superseded standard.
	Is the translation of the EU declaration of conformity the manufacturer's responsibility when he markets the equipment under his name or trade mark? Can the importer translate the declaration before he places the product on the market or can the distributor translate it before making it available on the market and provide	EU harmonisation legislation does not specify who has the obligation to translate. There can be a contractual arrangement between the manufacturer and the importer about who does the translation. In any case, in Annex IX to the PPE Regulation (EU) 2016/425 there is a compulsory, more detailed model of the EU declaration of conformity, which is already translated in all the EU official languages.

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	the translation together with the EU declaration of conformity of the manufacturer which is for example in English?	
	Must the translations of the EU declaration of conformity be signed by the manufacturer?	The EU declaration of conformity must be signed by the manufacturer (by an individual working for the manufacturer) or his authorised representative, and the employee's function shall also be indicated. If the translation of the EU declaration of conformity is not signed by the manufacturer, a copy of the original EU declaration of conformity signed by the manufacturer must also accompany the product, together with the translated version. *See also section 4.4. "EU declaration of conformity" of the "Blue Guide"*
Products subject to more than one EU legislation ***Article 15(3)***	Is it necessary to draw up several EU declarations of conformity when more than one act is applicable to a PPE product?	No. On the contrary, a single EU declaration of conformity is required whenever a product is covered by several pieces of EU harmonisation legislation (directives or regulations) requiring an EU declaration of conformity; such single declaration must refer to all of legislation applicable to the product and the related essential requirements. For this reason, if the PPE Regulation applies to a product as well, its reference should be included in the single or "global" EU declaration of conformity which must accompany the product. This should be checked by the importer or distributor. The single EU declaration of conformity can be one-page document listing the different directives or a dossier made up of relevant individual declarations of conformity (see recital 25). *See also § 4.4. "EU declaration of conformity" of the "Blue Guide"*
Products presenting a risk at national level ***Article 38***	What is the purpose of Article 38 which describes the procedure for dealing with products presenting a risk at national level?	The procedure described in Article 38 has different possible developments, towards the same result: ensuring that only compliant products are placed on the EU market. If upon request of the market surveillance authority the economic operator agrees to take the necessary corrective action (voluntary measures by the operator), the procedure ends here. In this case, if the market surveillance

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		authority considers that the risk goes beyond its national territory, the authority will inform the Commission and the other Member States of the results of the evaluation and the actions the economic operator intends to take. However, if the economic operator does not take corrective action as requested, the market surveillance authority shall take appropriate measures against the product (compulsory measures). In this case, the national authorities notify the measure to the Commission and to the other Member States, who have the possibility to object to it during a 3-month period. If no objection is raised, the measure is deemed to be justified. In this case all Member States are obliged to take appropriate action against the product on their territories. If objections are raised, the Commission needs to take a decision to determine whether the measure should be considered as justified or not (the Union safeguard procedure in Article 39). The purpose is that restrictive measures against the product are not an unjustified restriction of the free movement of goods, and that the same approach is followed in all MS where that particular product is present. Additionally, it is an information-sharing tool between market surveillance authorities: this exchange of information, although non-compulsory in the phase of voluntary corrective actions, is also expected to be submitted by the market surveillance authorities to the other Member States.
Three months' time to raise objections ***Article 38(7)***	How to compute the "three months'" time to raise objections by a Member State or the Commission against a measure taken by a Member State?	It is three calendar months, to be calculated according to the general provisions of Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, and in particular Article 3. For example: if a notification comes in on 15 September 2016, the day of notification does not count and the three months' time will end on 16 December 2016, 24:00h.
Compliant products which present a risk	What is the meaning of Article 40, especially with respect to Article 38?	The procedure of Article 40 has to be seen as exceptional case. In principle the essential requirements of the PPE Regulation (EU) 2016/425 are performance based and technology neutral. However, the Regulation takes into account the state of the art when it was drafted. It is possible that with the evolution of

TOPIC	QUESTION	ANSWER
Article 40		time, new technologies and the state of the art, the essential requirements do not cover all risks, in particular related to new products. This is the case foreseen in Article 40. In this case a product may formally comply with the essential requirements but nevertheless present a risk. Authorities must have to possibility to take restrictive measures against the product and this procedure allows them to do so. The difference to the "normal" safeguard procedure is that Article 40 deals with "compliant products", while Article 38 deals with products presenting a risk for not complying with the applicable requirements.
Formal non-compliance ***Article 41(1)***	Is the lack of CE marking, or the incorrect drafting of the EU declaration of conformity; a formal non-compliance?	Unless there are reasons to believe that the product presents a risk, there are cases where non-compliance with a number of administrative or formal requirements are defined as formal non-compliance by Article 41 of Regulation (EU) 2016/425. The lack of CE marking or the incorrect drafting of the EU declaration of conformity are expressly mentioned in Article 41(1) (b) and (d) respectively but it is rarely just a formal non-compliance: it could be related to more substantial safety issues. Formal non-compliances should thus lead to further investigation on the compliance of the product with the essential requirements. In any case, this Article 41 does not affect Article 38 (products presenting a risk). The CE marking, the EU declaration of conformity and the technical files can be defined as the cornerstone to place PPE products on the EU market. *See also § 7.4.5 "Corrective measures - Bans - Withdrawal - Recalls" in the "Blue Guide"*
Article 41(2)	How much should the national authorities wait for the non-compliance to continue before taking the appropriate measures to restrict or prohibit the product being made available on the market?	It depends on each case but always considering the proportionality principle in actions taken by national market surveillance authorities vis-à-vis economic operators, for non-compliances which "persist", during some time.
Transitional and final provisions	What are the implications of the dates of publication, entry into force, and applicability?	The **date of publication** is the date when the legal text is published in the Official Journal of the European Union and it is important to determine the date of entry into force of the legal act. The **date of entry into force** is usually

TOPIC	QUESTION	ANSWER
Articles 45, 46, 47, 48		expressed as the 20th day following publication of the legal text in the Official Journal of the European Union. It means that the EU rules have been adopted and published, thus producing legal effects. However, these rules are not necessarily mandatory on the date of entry into force. The date when they become mandatory is the **date of applicability**. The most important date is 21 April 2018, the date of applicability, from which Member States have to apply the provisions of the new Regulation (EU) 2016/425, according to Articles 48(2). Until that date, the previous Directive 89/686/EEC remains applicable. There are some points in the new Regulation which will become applicable earlier, namely articles 20 to 36 on the notification of conformity assessment bodies ("notified bodies") and article 44 on the committee procedure. It is important to clarify that the provisions on notified bodies are a possibility for earlier notification in case both parts (notifying authorities and notified bodies) are both ready, but this is by no means an obligation.
Transitional provisions for Member States	Which are the main tasks for Member States during the transition period?	The transitional phase is a phase intended to enable Member States to verify their national law in order to identify and remove possible contradictory national provisions. Furthermore, in order to ensure a smooth transition from the PPE Directive to the PPE Regulation, particularly with respect to conformity assessment bodies, the Regulation foresees that Member States can, from 21 October 2016, start notifying the conformity assessment bodies in accordance with Chapter V of the Regulation. The aim is to offer the possibility for Member States, as of 21 October 2016, to start the notification procedure. Therefore, the notifying authorities will have to check if the notified bodies are qualified under the new requirements foreseen in the Regulation. In addition, Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation and notify those rules to the Commission by 21 March 2018.

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Transitional provisions for notified bodies	Which are the main tasks for national notifying authorities and for notified bodies during the transition period?	As regards national notifying authorities, Member States must appoint notifying authorities at the national level (Article 21(1)). In addition, Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies (Article 23(1)). Furthermore, national notifying authorities should re-notify their conformity assessment bodies (notified bodies) before 21 April 2018, through the new devoted space in the Commission's NANDO database. In order to be notified, conformity assessment bodies have to comply with the requirements lay down in Article 24. The new PPE Regulation gives an opportunity to reinforce the competence, monitoring, information and co-operation activities of notifying authorities and notified bodies, according to the relevant provisions of the Regulation (Articles 20 to 36).
	Until which date is it possible to issue EC type-examination certificates according to Directive 89/686/EEC?	In principle EC type-examination certificates can be issued until the end of the transitional period, i.e. 20 April 2019. However, issuing EC-type examination certificates in the transition period may divert resources needed for the re-certification of products according to the Regulation. The Commission recommends issuing only EU type examination certificates after 21 April 2018.
	Can a notified body issue certificates according to the new PPE Regulation (EU) 2016/425 before 21 April 2018?	Yes. According to Article 48(2a) of the PPE Regulation, it shall apply from 21 April 2018, with the exception of Articles (inter alia) 20 to 36, which shall apply from 21 October 2016. According to Article 32(1), which is already applicable, notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII. It would result that a notified body may already perform all necessary tests and examinations so as to ensure compliance of a product with the PPE Regulation. A notified body would therefore be allowed to issue an EU-type examination certificate before 21 April 2018. These certificates however will only be of application for products placed on the market after the date the essential requirements of the PPE Regulation (EU)

TOPIC	QUESTION	ANSWER
		2016/425 are applicable, that is, 21 April 2018.
	Would it be possible to maintain the reference number of an EC-type examination certificate issued under Directive 89/686/EEC when it would be converted into an EU-type examination under Regulation (EU) 2016/425?	The numbering of certificates is under the autonomy of the notified body, the Regulation does not specify anything in this respect. If the practice of a notified body is to "re-issue" the whole certificate instead of issuing addendums, the certificate can continue carrying the same number and refer to the new Directive. In any case, the reference number of a certificate must allow to clearly identify it with respect to the approved type, according to Annex V(6).
Transitional provisions for manufacturers	Can products manufactured in accordance with Directive 89/686/EEC still be made available on the market after 21 April 2018?	Yes. There is a "transition period" in Article 47, a "period of overlapping" of one year between Directive 89/686/EEC and Regulation (EU) 2016/425. Products compliant with Directive 89/686/EEC can still be placed on the market before 21 April 2019, and products already in the distribution chain by that date can continue to be sold after that date. As indicated in § 2.2. "Making available on the market" of the "Blue Guide, **the concept of making available refers to each individual product, not to a type of product**, whether it was manufactured as an individual unit or in series. See above for more clarification on the concepts of "placing on the market" and "making available on the market".
	Is any transition foreseen for products which are in the scope of the Regulation but excluded from the Directive (oven gloves for private use)?	The transition provisions of article 47(1) apply also to these products, i.e. they can be placed on the market in accordance with the Directive before 21st April 2019.
Essential health and safety		The vast majority of EHSRs have not been modified or only slightly changed to improve wording and understandability as well as to reflect evolution of

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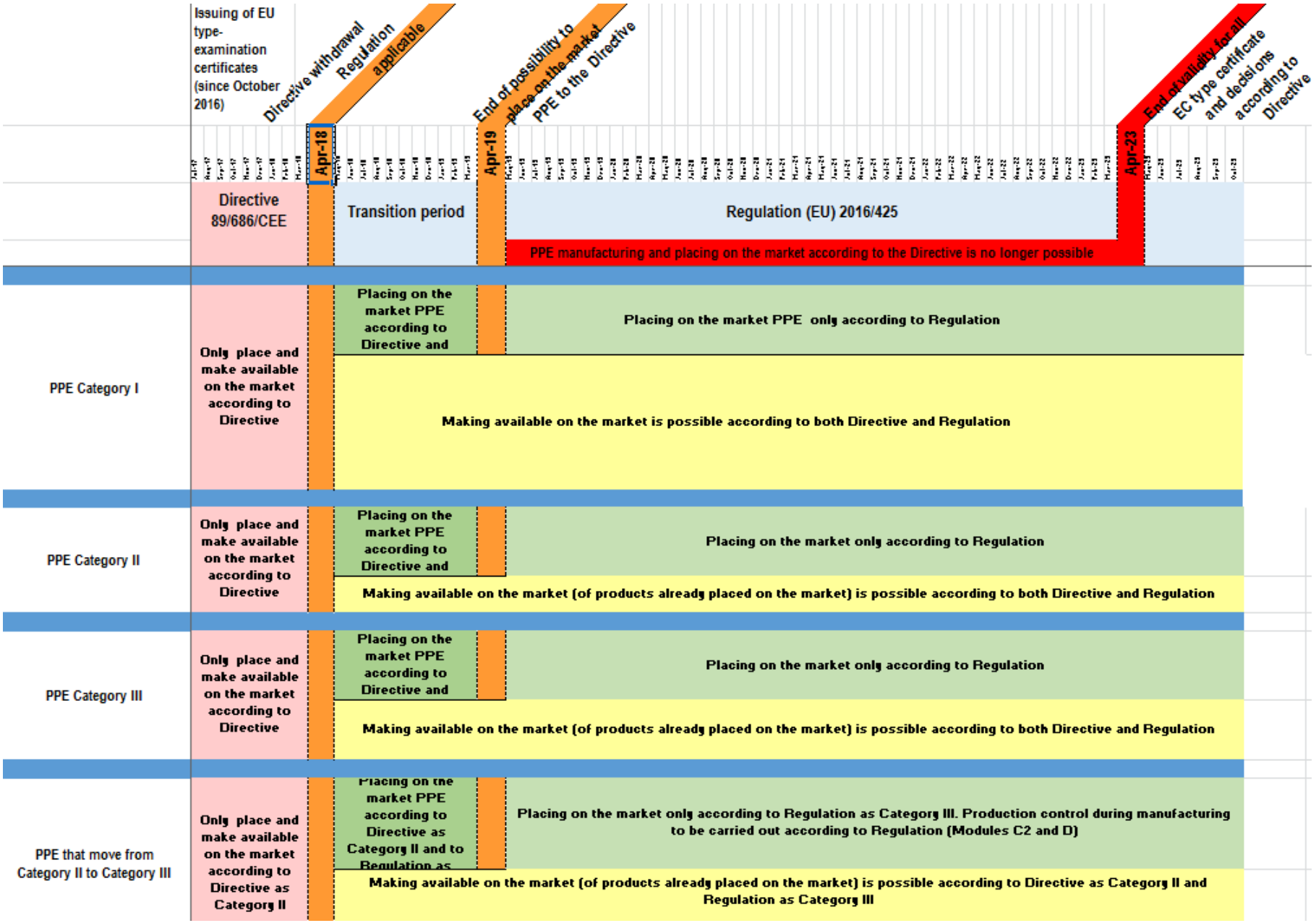
requirements ***Annex II***		technical knowledge; EHSR 1.3.4. "*Protective clothing containing removable protectors*" has been added.
EU-type certificates ***Annex V(6), (7) and (8)***	Is it necessary to limit the period of validity for EU-type examination certificates under Regulation (EU) 2016/425, for instance 5 years?	The new PPE Regulation (EU) 2016/425 includes, in points 6, 7 and 8 of Annex III, some references to validity, renewal and expiry of EU-type examination certificates. Such references were not present in the previous Directive 89/686/EEC and are derived from Decision No 768/2008/EC (Article 4(5)(e) and Annex II, Module B). The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years. In point 7.6 of Annex III, the conditions to be met for a simplified renewal procedure are indicated.

ANNEX: visual representation of the transition period


Issuing of EU type-examination certificates (since October 2016)
Directive withdrawal
Regulation applicable
End of possibility to place on the market PPE to the Directive
End of validity for all EC type certificate and decisions according to Directive
Apr-18
Apr-19
Apr-23
Directive 89/686/CEE
Transition period
Regulation (EU) 2016/425
PPE manufacturing and placing on the market according to the Directive is no longer possible
PPE Category I
Only place and make available on the market according to Directive
Placing on the market PPE according to Directive and
Placing on the market PPE only according to Regulation
Making available on the market is possible according to both Directive and Regulation
PPE Category II
Only place and make available on the market according to Directive
Placing on the market PPE according to Directive and
Placing on the market only according to Regulation
Making available on the market (of products already placed on the market) is possible according to both Directive and Regulation
PPE Category III
Only place and make available on the market according to Directive
Placing on the market PPE according to Directive and
Placing on the market only according to Regulation
Making available on the market (of products already placed on the market) is possible according to both Directive and Regulation
PPE that move from Category II to Category III
Only place and make available on the market according to Directive as Category II
Placing on the market PPE according to Directive as Category II and to Regulation as
Placing on the market only according to Regulation as Category III. Production control during manufacturing to be carried out according to Regulation (Modules C2 and D)
Making available on the market (of products already placed on the market) is possible according to Directive as Category II and Regulation as Category III

References for guidance

- The "Blue Guide" on the implementation of EU product rules (26/7/2016)

- "CERTIF" documents (non-binding interpretative documents issued by the European Commission):
  - CERTIF doc. 2008-002 - Differences between Conformity assessment modules as laid down in new approach (Decision 93/465/EEC - old modules) and as laid down in the new legal framework (Decision 768/2008/EC - new modules)
  - CERTIF 2009–03 - Orientations for selecting and implementing the modules (as laid down in Decision 768/2008 of the new legal framework) – SMES specificities
  - CERTIF 2009–04 - Introduction to conformity assessment and conformity assessment procedures of the new legal framework (as laid down in Decision 768/2008 of the new legal framework)
  - CERTIF 2009-08 - Using standards to assess the competence of conformity assessment bodies in the context of the New Legislative Framework
  - CERTIF 2010-05 Rev1 - Overview of market surveillance procedures (including safeguard clause mechanism) in the area of harmonised products
  - CERTIF doc 2010-06 - Notifications of Notified Bodies in NANDO – requirements of Regulation 765/2008 and Decision 768/2008
  - CERTIF 2012-06 REV1 – Notified Bodies - The use of the notified bodies number for activities not required by EU legislation
  - CERTIF 2013-11 REV1 Time frames for notification of NBs following the entry into force of the Alignment Package
  - CERTIF Guidance papers on accreditation (July 2014)
  - CERTIF 2015-01 REV2– The functioning of NANDO with regard to providing accurate information, objection periods, notification procedures and notified bodies groups

- **PPE 2016/425 Guidelines** (in preparation; will be available on the PPE website on EUROPA)