	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.068 Version 02

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Question related to	☒ PPE Regulation	☐ EN/prEN:	☐ Other:
Article:	Annex: V	Clause: 4(f), 7.1, 7.2, 7.4(b)	

Key words:

State of the art / EU type examination

Question:

When conducting type-examination for a manufacturer, which standards and technical documents available to the notified body (NB) should be considered when assessing the conformity of a product, and considering "state of the art"?

Solution:

The manufacturer is solely responsible for identifying the standards and or technical documents they use to evidence compliance with the Essential Health and Safety Requirements (EHSR) – i.e. as part of their Risk Assessment. As such, they instruct the notified body on which standards and or technical documents to consider in initial type-examination.

The notified body cannot instruct a customer to apply a particular standard or technical document, however it can confirm through type-examination if any standard and or technical document chosen does or does not comply with the EHSR.

A European Commission policy officer in September 2019 confirmed that (See Annex 1 for original correspondence):

- "state of the art" has no legal definition,
- a manufacturer may use any European or even international standard they consider convenient and adequate,
- use of a Harmonised Standard conveys presumptions of conformity (in part) to the EHSR,
- use of any other standard(s) / technical specification(s) requires more in-depth and detailed Risk Assessment (Annex II, 4) to be presented and justified in the technical documentation.

In conducting the type-examination the notified body may consider any additional source / reference to that chosen by the manufacturer, when determining if the manufacturer has met the EHSR. [See PPER, Annex V, 4(f)]

Following issue of an EU type-examination certificate, a change to standards and or technical specifications may indicate that the approved type may no longer comply with its applicable EHSR – the manufacturer should be invited to consider this change in information, with respect to their compliance with the EHSR [See PPER, Annex V, 7.1 & 7.2 & 7.4(b)].
Where there is a safety concern (i.e. no longer complies with EHSR), the notified body has to confirm the manufacturer is aware of the change, and accepts to take action to address the change(s). A verbal commitment by the manufacturer is not sufficient for the NB.

The 'change' must be '*generally acknowledged*' to require notified body action on certificates issued. "*Generally acknowledged*" means widely available to economic operators and notified bodies, freely or through common purchase.

The table 1 below is for information purposes, and shows what common standards and or technical specification sources are available, and whether they could be considered 'generally acknowledged'.

Table 1		
Item No	Type / nature of document	Remarks – Generally Acknowledged?
1	Harmonised standard	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1.
2	RFU endorsed by European Commission (horizontal and vertical RFUs)	Publicly available, via EC's PPE homepage, for free: https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment-ppe_enTo be considered by NBs as per PPER Annex V, 7.1.
3	Published European standard (CEN/CENELEC)	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1
4	HC validated RFU (not yet endorsed by European Commission, nor subject to comment(s) from PPE EG)	Publicly available, via ppe-rfu.eu website, for free. To be considered by NBs as per PPER Annex V, 7.1.
5	VG validated RFU (not yet endorsed by European Commission, nor subject to comment(s) from PPE EG)	Publicly available, via ppe-rfu.eu website, for free. To be considered by NBs as per PPER Annex V, 7.1.
6	Other National / International Standards	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1.
7	Industry Standards / Technical Specifications	Publicly available, typically for free. To be considered by NBs as per PPER Annex V, 7.1.
8	Private developed protocol by NB for specific product	Private / Confidential to single Manufacturer. To be considered by NBs in PPER Annex V, 7.1.
9	Standard Project (TS, pr or other drafts)	Not to be considered by NBs in PPER Annex V, 7.1.

Annex 1

Email: Answer from European Commission to the question of "state of the art" definition

Dear Mr XXX,

Many thanks for your interesting message. I reply as the Policy Officer in charge of Regulation (EU) 2016/425 on personal protective equipment ("the PPE Regulation"); I apologise for the late reply, due to the internal reattribution of your message.

As provided for in Article 14 of the PPE Regulation, "PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof". Therefore, presumption of conformity is conferred only by harmonised European standards ("harmonised" as defined in Article 2(1)(c) of Regulation (EU) 1025/2012 on European standardisation: "'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation") which reference is published in the OJEU, irrespective whether it is already superseded by another standard which reference is not published yet, for any reason.

Beside these legal references, the concept of "state of the art" is not legally defined. In the PPE Regulation it is just mentioned as a generic reference (see Recitals 27 and 28, the "Preliminary remarks" of Annex II on essential health and safety requirements, and others) and then some comments and considerations on that can be found in the "PPE Regulation Guidelines" (p. 87) and in section § 4.1.2.5. of the horizontal "Blue Guide". In any case, such considerations on the "state of the art" cannot prevail on the legal value of the references of standards published in the OJEU.

Notified bodies, as well as manufacturers, can use any European or even international standards they consider convenient and adequate to their needs; but, if not cited in the OJEU, such use does not confer presumption of conformity, and it is necessary to carry out a more in-depth and detailed risk assessment, adequately presented and justified in the technical file, to demonstrate that the technical solution used is able to comply with the essential health and safety requirements laid down in the legal text.

If deemed necessary and useful, this point could be widely presented at the next meeting of the HCNB for PPE, on 28-29 November 2019, to ensure a common understanding and harmonised approach for all the notified bodies.

Best regards

YYY Policy Officer Mechanical Engineering