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

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

Regulation (EU) 2016/425 on personal protective equipment:

Validity of an EC type-examination certificate and revision of harmonised standards

I. Background

In the case of the revision of harmonised standards and the subsequent citing of their references in the OJEU, market surveillance authorities and customs authorities in the Member States had different interpretations regarding the placing on the market of PPE with a valid EC type-examination certificate, based on a previous version of a harmonised standard, after the end of the transition period given in the OJEU for the superseded standard.

II. The "Blue Guide" and Regulation (EU) 2016/425

The issue of the revision of harmonised standards is a horizontal one in EU product legislation. The "*Blue Guide on the implementation of EU product rules*"[1], in point 4.1.2.6. 'Revision of harmonised standards', provides useful guidance on the implications on already issued certificates of the removal of old references of harmonised standards from the OJEU and the subsequent citing of their new versions in the OJEU.

According to the "Blue Guide", *'the removal of the reference of a harmonised standard from the Official Journal after its revision does not automatically invalidate existing certificates issued by notified bodies*'. In fact, the revision of the harmonised standards *per se* does not have by default impact on the validity of the EC type-examination certificate, and '*products produced according to the old certificate may still benefit from the continuing conformity with the essential requirements and may continue to be placed on the market until the end of validity of the relevant certificates issued by notified bodies*'.

Then, the "Blue Guide" clarifies that '*however, manufacturers must assess the extent of the changes to the superseded version of the standard. The kind of action to be taken by the manufacturer depends on the nature of the changes in the harmonised standards, in particular whether these changes are material with regard to the coverage of the essential requirements and whether they concern the product in question*'.

This is reflected in Article 8(1) and (4) of the PPE Regulation which requires manufacturers to ensure that PPE '*has been designed and manufactured in accordance with the applicable essential health and safety requirements*', and '*series production*' must '*remain in conformity*

[1] OJ C 272, 26.7.2016, p. 1 http://ec.europa.eu/DocsRoom/documents/18027/.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: BREY 10/160 - Tel. direct line +32 229-95941

GROW-PPE@ec.europa.eu

with the Regulation'. The manufacturers shall therefore assess changes in the harmonised standards by reference to which the conformity of the PPE is declared and shall adequately take them into account.

Furthermore, concerning EU type-examination, Annex V, point 7.3 of the Regulation sets down that '*the manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art*'. Additionally, point 7.2 requires that the '*The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate*'.

The "Blue Guide" also clarifies that '*the notified body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly*'.

This obligation of the notified bodies is also reflected in PPE Regulation, in particular in Annex V, point 7.1.

III. Conclusion

As a general principle, the removal of the reference of a superseded harmonised standard from the OJEU after its revision by a superseding harmonised standard does not automatically invalidate existing certificates issued by notified bodies making reference to such superseded harmonised standard.

The necessary information should be included in the revised standard itself, and the relevant European Standardisation Organisation (CEN, CENELEC) in charge of the development and publication of a new harmonised standard, should indicate, in the foreword or in an annex, the nature of the changes made with respect to the superseded version. Such given information may not affect all the products covered by the standards, but it would be necessary to apply it to the specifically concerned products.

Manufacturers must carry out a specific assessment on the extent of the changes to the superseded version of the standard they used as indicated in the EC type-examination certificate, in particular whether these changes are substantial with regard to the coverage of the essential health and safety requirements the product in question must comply with. They should share and discuss their assessment with the relevant notified body with a view to reach agreement about the impacts of the change in the standard. Such agreement should be documented.

If the specific design (type) was concerned by the changes introduced by the revised harmonised standard, then a further assessment, as well the revision of the certificate and of the corresponding documentation are needed, to ensure compliance with the applicable essential requirements.

On the contrary, where a revision of a harmonised standard is limited, for instance, to a 'formal' or an 'administrative exercise' and it seems unlikely that such revision would have impacts on

the product's compliance with the essential requirements, such certificates could continue to be considered valid until their expiry date.

In any case, an assessment on a case by case basis is needed to be carried out by the manufacturer who is under an obligation to ensure that the PPE has been designed and manufactured in accordance with the essential health and safety requirements of the applicable PPE legislation. The documentation of the assessment carried out should be added to the relevant technical documentation of the product, in order to clearly explain that while the superseded version of the standard no longer provides presumption of conformity, compliance with the essential requirements is nevertheless still ensured.