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

Guidance document on the implementation of Article 47 on transitional provisions[1]

I. Regulation (EU) 2016/425

Regulation (EU) 2016/425 on personal protective equipment (herewith referred to as 'the Regulation') was published in the *Official Journal of the European Union* of 31 March 2016 and entered into force on the 20th day following this publication, i.e. on 20 April 2016.

However, the Regulation will be fully applicable from 21 April 2018, with the exception of Articles 20 to 36, on notification of conformity assessment bodies, and of Article 44, on Committee procedure, which apply from October 2016. In addition, Article 45 (1) on penalties applies from 21 March 2018.

In addition to the entry into force and application, the Regulation makes provision for a transition period. Article 47 (1) of the Regulation sets down that *'Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April 2019'*. Article 47 (2) lays down that *'EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date'*.

The transitional period has raised a number of questions and doubts by market surveillance authorities of the Member States on how to practically implement those provisions, in particular with respect to the validity of EC type-examination certificates.

The following considerations, which have the support of the Member States and stakeholders that are represented in the PPE working group, are intended to guide a uniform practise throughout the Internal Market.

II. Questions relating to the implementation of Regulation (EU) 2016/425

II.1. Transitional period for PPE

The Regulation foresees a specific transitional regime for PPE: a transitional period of 1 year (21 April 2018 to 20 April 2019) where both, the old Directive and the new Regulation, are applicable.

[1] This guidance document is not legally binding. The ultimate interpretation of European Union law lies with the European Court of Justice.

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

Mario.GABRIELLI-COSSELLU@ec.europa.eu – GROW-PPE@ec.europa.eu

Thus, in accordance with Article 47 (1), PPE designed and manufactured in accordance with Directive 89/686/EEC can still be placed on the market until 21 April 2019 and in principle EC type-examination certificates in accordance with Directive 89/686/EEC can be issued until the end of the transitional period, i.e. 20 April 2019. As the Regulation is applicable from 21 April 2018, from that date manufacturers can start placing on the market PPE in accordance with the Regulation.

II.2. Compliance of PPE with the new Regulation

As from 21 April 2019, all personal protective equipment placed on the market shall comply with the requirements of the PPE Regulation, being accompanied by the EU declaration of conformity (Article 15, Annex IX) and instructions for use as foreseen under Annex II, point 1.4, based, for category II and III products, on the EU type-examination certificate (Annex V) and, when applicable, on quality assurance approval decisions in accordance with the relevant conformity assessment procedures (Article 19, Annexes V, VII and VIII).

II.3. Validity of certificates

In general, certificates and approval decisions issued after the date of applicability of a revised legislation have to be in line with that new legislation. However, the legislation may specifically foresee that certificates and approval decisions issued under the repealed legislation shall be valid also under the new legislation until a due date. Such a provision is usually inserted when the essential safety requirements remain substantially the same in the revised legislation.

In the specific case of the PPE Regulation, Article 47 (2) provides that EC type-examination certificates and approval decisions issued under Directive 89/686/EEC, before 21 April 2019, remain valid until 21 April 2023 unless they expire before that date.

This provision was the subject to different interpretations, notably whether it was applicable to all EC type examination certificates issued under Directive 89/686/EEC or only to those issued during the transitional period.

It is important to note that this question only concerns the validity of the certificate. It must be absolutely clear that as of 21 April 2019 any PPE placed on the market must be in full conformity with the requirements of the Regulation. The question at stake here is whether economic operators are allowed to base their EU declaration of conformity (which must also comply with the requirements of the new Regulation) on a certificate issued under Directive 89/686/EEC before 21 April 2019.

In light of the discussions with the Member States and stakeholders represented in the PPE working group, we can draw the following conclusions:

The rationale for introducing Article 47 (2) was that the essential requirements of the PPE Directive have remained largely unchanged. Article 47 (2) is meant to be a real transitional provision with the purpose of facilitating the smooth transition to the new legal regime which has introduced the 5 year validity period for EU type-examination certificates. Any other interpretation would be overly restrictive not corresponding to the intention of the co-legislators.

For this reason it is suggested to apply the following approach:

As a general rule, PPE may be placed on the market after the full applicability of the PPE Regulation (21 April 2019) on the basis of an EC type-examination certificate and/or an approval decision in accordance with the PPE Directive, until 21 April 2023. After that date the validity of the certificate/approval decision expires in any case and a new certificate/approval decision in accordance with the Regulation is needed.

However, this approach is not applicable in the following cases:

- one or several applicable essential health and safety requirement(s) in the Regulation has/have changed on substance[2] to the extent that a higher level of protection than the Directive is required. In this case a certificate issued under the PPE Directive cannot be used to demonstrate compliance with the Regulation and an EU type-examination certificate under the Regulation must be issued;
- the design and/or manufacture of the PPE has changed since the last EC type-examination;
- the generally acknowledged state of the art which is reflected by European harmonised standards has changed (updated versions with significant changes on safety clauses, withdrawal of current versions, etc.) and therefore it may imply that the product may not be compliant.

[2] Instructions for use are part of the essential safety requirements and these requirements have been slightly changed. However the changes are minor and cannot be seen as affecting the safety level of the product. It would be disproportionate to require that all PPE should be subject to recertification or re-issue of the EC type-examination certificates only because of these minor changes.