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 (PPE):

Approval decisions under the PPE Regulation based on EC type-examination certificates

I. Background

Article 47 of the Regulation provides for a transitional period and the first paragraph 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(1) should be interpreted as allowing for the possibility of bodies notified under Directive 89/686/EEC to continue to issue decisions regarding conformity of products with that Directive until 20 April 2019. This is fully in line with the contents of the 'Guidance document on the PPE transition from Directive 89/686/EEC to Regulation (EU) 2016/425' and the 'Guidance document on the implementation of Article 47 on transitional provisions', then included in the 'PPE Regulation Guidelines - 1st Edition - April 2018'.

Article 47, second paragraph, extends the validity of the EC type-examination certificates and approval decisions issued under Directive 89/686/EEC and lays down that they '*[…] shall remain valid until 21 April 2023 unless they expire before that date*'.

The transitional period and the link between EC type-examination certificates and approval decisions, and their validity and expiry before and after the transitional period, have raised a number of questions and doubts by market surveillance authorities of the Member States and notified bodies.

The following considerations are intended to guide a uniform practise throughout the EU Internal Market.

II. Approval decisions issued before the applicability of the Regulation

Approval decisions issued on the basis of Article 11A of Directive 89/686/EEC (module C2) are normally valid for one year, i.e. issued after each supervised product checks which are performed at least once a year.

On the other hand, approval decisions based on Article 11B of Directive 89/686/EEC (module D) are normally valid up to three years, i.e. corresponding to the approval of the Quality Management System according to EN ISO 9000 or other similar systems. The approval decision

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remains valid if no serious non-conformities are found in the audits performed at least once a year.

There has been the question on whether those approval decisions issued under Directive 89/686/EEC (Article 11A and Article 11B) can be valid for 1 or 3 years after the end of the transitional period, e.g. after 20 April 2019.

The reply is affirmative. On the basis of Article 47(2) of the Regulation, it is considered that approval decisions are valid until the end of the validity of the underlying EC type-examination certificate, it is to say, until 21 April 2023 unless they expire before that date.

III. Approval decisions issued during the transitional period

A) Approval decisions issued during the transition period under Directive 89/686/EEC

According to the interpretation of Article 47(1) of the Regulation referred above, approval decisions under Directive 89/686/EEC can be issued during the transition period, i.e. between 21 April 2018 and 20 April 2019, and remain valid until 21 April 2023, unless they expire before.

This is in line with the wording of Article 47(2) which extends the validity of both the EC type-examination certificates and the approval decisions.

B) Approval decisions issued under Regulation (EU) 2016/425 and based on an EC type-examination

Another question that has been raised is whether a notified body can or not issue an approval decision under Regulation (EU) 2016/425 which is based on an EC type-examination under Directive 89/686/EEC.

The reply is affirmative as it is considered that according to Article 47(2), there is a link between the EC type-examination and the approval decisions. An EC type-examination certificate is, therefore, regarded as a basis for issuing new approval decisions, which meanwhile have expired, until the end of the validity of the correspondent EC type-examination certificate. *(See also the 'Guidance document on the implementation of Article 47 on transitional provisions' with respect to validity of certificates in case of changes in the essential health and safety requirements, in the design and/or manufacture of the PPE and in the state of the art)*

C) Approval decisions expired during the transitional period and the responsible notified body is not re-notified under the Regulation

An additional question that has been raised concerns the approval decisions expiring during the transitional period and issued by a notified body which has not been re-notified under the Regulation. In such a hypothesis, can the body, notified under the Directive but not under the Regulation, renew the approval decision under Directive 89/686/EEC?

The reply is affirmative, as during the transitional period and before 21 April 2019, products in conformity with Directive 89/686/EEC can be still placed on the market, so the Directive is practically still applicable and notified bodies can still perform their activities during this period, according to the interpretation of Article 47(1) of the Regulation referred above. Certificates and approval decisions issued by those notified bodies under Directive 89/686/EEC remain valid until 21 April 2023 unless they expire before that date.

However, if the approval decisions expire after 20 April 2019, the approval decisions can be renewed only by a body notified under the Regulation.

Therefore, after 20 April 2019, the bodies which were notified under Directive 89/686/EEC and which were not subsequently re-notified under the Regulation, can no longer issue or renew approval decisions.