Guidance on transition period from PPE Directive 89/686 to PPE Regulation 2016/425

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The publication of the PPE Regulation 2016/425 brought several questions concerning the transition period and more particular concerning the continued validity of EC Type Examination certificates.

Article 47.1 provides for a transition period from 21/4/2018 till 21/4/2019. During this period it is possible to place PPE on the market either in compliance with the Directive or with the Regulation.

Article 47.2 of the Regulation stipulates that EC Type Examination certificates remain valid till 21/04/2023 or till their expiry date whichever comes first. However, this does not mean that PPE placed on the market after the end of the transition period have not to comply with the Regulation, even if an EC Type Examination certificate is used to prove compliance.

In order to clarify for manufacturers and other stakeholders what to do, the European Safety Federation (ESF) developed a flow chart providing guidance on what to do in different specific situations. We are convinced that following this flow chart, manufacturers continue to prove compliance with the applicable legislation as well as continue to place PPE on the market that are safe and providing the required protection for the user. And this without disturbing the market or creating capacity issues at both notified bodies and manufacturers.

To bring PPE in compliance with the Regulation, manufacturers have at least to make some changes to markings, instructions and Declaration of Conformity (DoC). These have to be checked for each PPE, but the main changes are:

- For marking : adding the postal address of the manufacturer. In case of import from outside the EU, also the name, registered trade name or trade mark and the postal address of the importer have to be indicated on the PPE (or at least on the packaging or documents accompanying the PPE).
- For instructions : making sure the risk against which the PPE is designed to protect and the references of the applied harmonised standards are included. Change the reference of the legislation to the Regulation 2016/425 and either add the full text of the DoC or an internet link where the DoC can be obtained easily. For cat III PPE, add also the information of the NB responsible for module C2 or D next to the information of the NB responsible for the type examination.
- For DoC : draw up a new DoC referring to the Regulation 2016/425 according to annex IX of the Regulation.

For category II and III products, these (administrative) changes have to be informed to the Notified Body responsible for the type examination procedure. For any other change to PPE, the manufacturer shall inform the Notified Body and await its confirmation that the changes can be made or, when necessary, the issue of a reviewed EU type examination certificate.

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create the technical documentation with the necessary proof for conformity assessment.

(1) check how to prove compliance with the changed EHSR (might be that there is no (harmonised) standard available)
(2) apply with NB for recertification taking into account the changed EHSR in the technical documentation

same as for Cat II + taking into account additional production control module C2 or D

(1) perform the necessary changed testing
(2) bring the technical file in compliance with the Regulation before 21/04/2019
(3) apply for reviewed EU type examination certificate before 21/04/2019.

same as for Cat II + taking into account additional production control module C2 or D before 21/04/2019

bring the product in compliance with Regulation by adapting marking / UI / DoC before 21/04/2019

remark: in this case, it is good practice to double check the relevance of the impact of possible changes in harmonised standards and state of the art, especially in the case of very old certificates.

recertification is necessary, this can be based on existing EC certification and testing (simplified procedure in annex V 7.6 can be a guidance for the recertification) with addition of specific procedures for Cat III (module C2 or D) and the necessary adaptations to marking / UI / DoC before 21/04/2019

same as for Cat II + agree with NB to use module C2 in stead of 11A or module D in stead of 11B. Technical file will have to be updated with the changes.

remark: type examination certification is always based on the current version of the applied harmonised standards.