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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are there changes to the EHSR for the product? (change in annex II of the Regulation compared to annex II of the Directive)

YES → conformity assessment has to be revised before 21/04/2019. → which category is the PPE?

- Cat I → create the technical documentation with the necessary proof for conformity assesment
- Cat II → (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
- Cat III (including those products changing from cat II to cat III) → same as for Cat II + taking into account additional production control module C2 or D

NO → has there been a change in the state-of-the art? Has an applied (harmonised) standard been revised?

YES → evaluate the change and act accordingly: has the change a relevant impact on the protection level of the product? (Change in requirement for product/ technical change in test method (change in method, change in callibration, ...)

YES → which category is the PPE?

- Cat I → (1) perform the necessary changed testing
  (2) bring the technical file in compliance with the Regulation before 21/04/2019
- Cat II → (1) review with the NB the changes and neccesary new/additional testing
  (2) bring the technical file in compliance with Regulation
  (3) apply for reviewed EU type examination certificate before 21/04/2019.
- Cat III (including those products changing from cat II to cat III) → same as for Cat II + taking into account additional production control module C2 or D before 21/04/2019

NO (from has there been a change...) and NO (from evaluate the change...) → which category is the PPE?

- Cat I → bring the product in compliance with Regulation by adapting marking / UI / DoC before 21/04/2019
- Cat II → does the EC type examination certificate have an expiry date?
  - YES → when is the expiry date of the EC type examination certificate?
    - after 21/04/2019 → bring the product in compliance with the Regulation by adapting marking / UI / DoC and inform the NB - apply for renewal of the certificate well on time (6 months before expiry date)
    - between 04/2018 and 04/2019 → contact the NB for renewal of the certificate to the Regulation at least 6 months before the expiry date
    - before 04/2018 → expiry of the certificate will be before 04/2018 and thus EC certificate should be renewed before 04/2018 (based on Directive) - discuss with your NB pragmatic approach for renewal to Directive and Regulation taking into account the requirements of the Regulation on marking, UI and DoC
  - NO → still valid till 21/04/2023 → bring the product in compliance with Regulation by adapting marking / UI / DoC with information to NB and apply for renewal of certificate well before 04/2023.
    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.
- change from Cat II to Cat III → 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
- Cat III → 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

has the NB applied for notification under Regulation

YES → did NB get notification?

- YES → no problem to proceed to work with them
- NO → if notification is not foreseen before your deadlines, consider changing to a different NB

NO → choose different NB and make sure to transfer files from old NB to new NB

DO NOT KNOW → contact your NB. Depending on the given reason for lack of answer from the NB (e.g. lack of decision at National level or NB, Brexit, ...): consider changing to other NB

has a harmonised standard used for conformity assessment been revised because of safety problems (e.g; after a formal objection?

- YES → this might lead to withdrawal of the type examination certificate - review of existing certificate is certainly necessary - contact your NB - see above for different scenarios.
- NO → proceed as in flowchart depending a category

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