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REGULATION (EU) 2016/425 ON PERSONAL PROTECTION EQUIPMENT: PLACING ON THE MARKET AFTER B+C2 CONFORMITY ASSESSMENT PROCEDURE

Background of the discussion

The PPE AdCo group asked the Commission services to clarify, for PPE category III that follow the conformity assessment procedure B+C2, when can the placing on the market happen: after the manufacturer has lodged an application for the product checks, or after the first product check has been performed. The Commission shared its opinion on the subject. The HCNB indicated afterwards that the general practice of the vast majority of the notified bodies is to authorise the manufacturers to the place PPE on the market once the manufacturer has performed the module B assessment is done and has signed a contract for the product checks.

The intention of this paper is to provide the stakeholders with a detail explanation of the relevant provisions of the applicable legal framework to clarify the subject.

Applicable legal framework

As for the other EU legislative acts under the "New Approach" / "New Legislative Framework" covering products in the internal market, two important elements of the PPE Regulation are:

- the legislative requirements governing the characteristics of the PPE covered, and
- the conformity assessment procedures the manufacturer carries out in order to demonstrate that a PPE, **before it is placed on the market**, conforms to these legislative requirements.

Conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a PPE have been fulfilled.

A PPE is subjected to conformity assessment both during the design and production phase and distinct modules are used for each phase:

Article 8(2) of the PPER lays down the obligation of the manufacturer to carry out a conformity assessment procedure:

> *"Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and **carry out the applicable conformity assessment procedure referred to in Article 19** or have it carried out.*

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16."

Article 19 of the PPER states which is the applicable conformity assessment procedure for each risk category. PPE Category III is subject to either B+C2 or B+D conformity assessment procedure. Module B is the part of the conformity assessment procedure that takes place during the design phase while modules C2 or D take place during the production phase:

"The conformity assessment procedures to be followed for each of the risk categories set out in Annex I are as follows:
[...]
(c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:
*(i) conformity to type based on internal production control plus supervised product checks at random intervals (**module C2) set out in Annex VII**;*
(ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.
By way of derogation, for PPE produced as a single unit to fit an individual user and classified according to Category III, the procedure referred to in point (b) may be followed."

Point 1 of Annex VII of the PPER, defines the obligations of the manufacturer with regard to module C2:

*"1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the **manufacturer fulfils the obligations** laid down **in points 2, 3, 5.2 and 6,** and ensures and declares on his sole responsibility that the **PPE, which has been subject to the provisions of point 4**, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation."*

Point 2 of Annex VII of the PPER, lays down the obligation of the manufacturer to perform the internal production control:

"2. Manufacturing
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type- examination certificate and with the applicable requirements of this Regulation."

Point 3 of Annex VII of the PPER, lays down the obligation of the manufacturer to lodge an application with a notified body for supervised product checks. It indicates that is shall be done before placing the PPE on the market. This seems to be the main source of conflict as some interpret this as necessary and sufficient condition after the internal production control to allow the manufacturer to affix the conformity marking and to place the product on the market, while as it is indicated in point 1 of Annex VII the manufacturer has to fulfil also other obligations:

"3. Application for supervised product checks at random intervals

***Before placing PPE on the market**, the manufacturer shall lodge an application for supervised product checks at random intervals with a single notified body of his choice.*
The application shall include the following:
[…]"

Point 4 of Annex VII of the PPER, sets out the provisions to carry out the product checks. Particularly point 4.2 sets a deadline of one year after the date of issue of the EU type- examination certificate (and not after the date of placing on the market) for the first product check. As indicated in point 1 of Annex VII, PPE shall have been subject to the provisions of this point as part of the conformity assessment procedure:

"4. Product checks
4.1. The notified body shall carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.
*4.2. The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The **first product checks** shall be carried out no more than **one year after the date of issue of the EU type-examination certificate**.*
[…]"

Point 5 of Annex VII of the PPER, sets out the provisions in relation to the test reports. Particularly **point 5.2** indicates the obligation of the manufacturer to be in possession of the test report of the product check for a period of 10 years after placing the product on the market. Point 5.3 links the obligation of affixing the notified body's identification number to the test report:

"5. Test report
5.1. The notified body shall provide the manufacturer with a test report.
5.2. The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.
5.3. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process."

As indicated Article 41(f) of the PPER the fact that the technical documentation is either not available or not complete is a reason for a formal non-compliance of the product, and if it persists the Member States shall take appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.

Point 6 of Annex VII of the PPER lays down the obligation to affix the CE marking and the notified body's identification number as a consequence of the conformity assessment procedure, and also the obligation to draw up a written EU declaration of conformity. By affixing the CE Marking the manufacturer declares on his sole responsibility that the product conforms to all applicable PPER requirements, and that the appropriate **conformity assessment procedure has been successfully completed** (see section 4.5.1.3. of the Blue Guide):

"6. CE marking and EU declaration of conformity
6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to

each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

[…]"

Decision No 768/2008/EC, Regulation (EC) No 765/2008 and now also Regulation (EU) 1020/2019 form the New Legislative Framework. Decision No 768/2008/EC lays down common principles and reference provisions for the marketing of products, and are intended to apply across sectoral legislation. In particular, Decision No 768/2008/EC lays down the general guidelines and detailed procedures for conformity assessment. Point 3 of the provisions for module C2 in Annex II of Decision No 768/2008/EC, states that the sample for the product checks shall be taken on site before the placing on the market:

"[…]An adequate sample of the final products, ***taken on site by the notified body before the placing on the market****, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument.[…]"*

Conclusion

According to the provisions of the PPER and Decision No 768/2008/EC above indicated, it can be stablished that while the condition of lodging an application with a notified body before placing the product on the market is necessary (point 3 of Annex VII), it is not sufficient to subsequently affix the conformity marking and place the product on the market. The manufacturer shall fulfil the rest of the obligations laid down in point 1 of Annex VII, which include among others, the need to be in possession of the test report provided by the notified body (point 5.2. of Annex VII). This can only happen after the first product check has been performed.