



HCNB PPE position on EU type-examination & state of the art (history of PPE-R 00.068)

The HCNB PPE has invested considerable time developing PPE-R 00.068, resulting in multiple versions. Unfortunately, the detailed analytical process undertaken to reach this solution was subsequently lost. The HCNB PPE believes this analysis represents a valuable piece of information that should be preserved.

From PPE-R 00.068 V04:

The manufacturer is solely responsible for identifying the standards and or technical documentations they use to evidence compliance with the Essential Health and Safety Requirements (EHSR) – i.e. as part of their Risk Assessment. As such, they instruct the notified body on which standards and or technical documentations to consider in initial type-examination.

The notified body cannot instruct a customer to apply a particular standard or technical documentation, however it can confirm through EU type-examination if any standard and or technical documentation chosen does or does not comply with the EHSR.

In conducting the EU type-examination, the notified body may consider additional sources / references to that chosen by the manufacturer, when determining if the manufacturer has met the EHSRs [See PPER, Annex V, 4(f)], and identify any non-compliance or risks not covered.

Following issue of an EU type-examination certificate, a change to standards and or technical specifications may indicate that the approved type may no longer comply with its applicable EHSR – the manufacturer should be invited to consider this change in information, with respect to their compliance with the EHSR [See PPER, Annex V, 7.1 & 7.2 & 7.4(b)].

Where there is a safety concern (i.e. no longer complies with EHSR), the notified body has to confirm the manufacturer is aware of the change, and accepts to take action to address the change(s). A verbal commitment by the manufacturer is not sufficient for the NB.

The 'change' must be 'generally acknowledged' to require notified body action on certificates issued. "Generally acknowledged" means widely available to economic operators and notified bodies, freely or through common purchase.