

Position paper of the Horizontal Committee of Notified Bodies in the field of PPE



Consequences of the revision of harmonised standards

Some customs authorities and Market Surveillance authorities seem to expect that products always comply with the latest harmonised standards. This is a cause of concern. The following points need to be considered in order to ensure that clear procedures can be defined for manufacturers and notified bodies to follow.

- There is no general obligation for the withdrawal of EC type examination certificates following the revision of a harmonised standard.
- It is generally accepted that the certification of new products should always follow the latest version of the harmonised standard.
- Unless there have been safety concerns with the old harmonised standard, e.g. following a formal objection, PPE produced in accordance with the old harmonised standard can still be put on the market. In those cases certificates shall not be withdrawn.
- If certificates based on the old version of a harmonised standard were to become invalid after publication of a revised version, there would be an imbalance between products certified against a harmonised standard and products that do not follow a harmonised standard.
- Harmonised standards should remain the preferred basis for EC type examination.
- A 5 year limit for the validity of certificates can indirectly cause manufacturers to up-date their certificates to take account of revised harmonised standards.
- The revision of a harmonised standard may reflect a change in the state of the art. In this case, a revision may justify that all affected certificates are upgraded within an agreed period and where this is not achieved, certificates will be withdrawn.
A clear procedure is needed, in the standardisation process, to decide when this is the case, by listing the changes in a harmonised standard and assessing their relevance, e.g. EN 13463-5:2011.
- If a harmonised standard contains important changes that justify the withdrawal of certificates, it should be acknowledged that PPE manufacturers and notified bodies may need time to adapt their products and certificates to new requirements. Therefore, suitable transition periods should be envisaged before enforcement action is taken.
- Manufacturers and other stakeholders cannot always be expected to be fully aware of the imminent publication of a revised harmonised standard. The reference time for actions (withdrawal of certificates, market surveillance activities, etc.) therefore cannot be before availability of the revised harmonised standard.
- There should be a harmonised procedure for new production and products that are already in the supply chain.
- However, if notified bodies are aware of the imminent publication of a revision of a harmonised standard, which will require further action, they should inform the manufacturer about the possible consequences of the publication.

There is a need for a common approach by all Member States to ensure that there is a good basis for the work of manufacturers, notified bodies and the authorities.

Agreed at the meeting of the Horizontal Committee of Notified Bodies for PPE
on 22 November 2013