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Conformity assessment without current or listed harmonised European standards (hEN)

Strategies and measures for manufacturers to fulfil essential requirements of EU product regulations

If products are to be sold on the European Single Market, every manufacturer is obliged to assess and document conformity with the applicable legislation. The conformity assessment[1] must take place before the product is placed on the market[2]. This is the first time the product is made available on the market, regardless of whether this takes place free of charge or as part of a sale.

Harmonised European Standards (hEN) are an essential instrument for demonstrating the conformity of products with the essential requirements of the EU harmonisation directives and regulations. If hENs listed in the Official Journal of the EU are applied in full, a presumption of conformity (POC) is triggered. By means of this POC, the conformity of the product with the technical requirements of the legal act (the so-called essential requirements) is assumed. However, if no hEN is available or an existing hEN no longer reflects the current state of the art[3], manufacturers must take alternative measures.

This guide explains possible steps for dealing with these challenges, focussing on the technical conformity assessment by manufacturers. Special requirements for products for which the involvement of a notified body is mandatory are not part of this guide. Formal requirements of EU legislation are also not dealt with in detail.

Differentiation between standards and technical specifications in accordance with the Standardisation Regulation (EU) 1025/2012:

'standard' means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

1. 'international standard' means a standard adopted by an international standardisation body;
2. 'European standard' means a standard adopted by a European standardisation organisation;
3. 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;
4. 'national standard' means a standard adopted by a national standardisation body;
5. 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process, service or system

1. Importance of harmonised standards

Harmonised standards are mandated by the European Commission and serve to technically specify the abstract legal requirements from the CE-relevant directives (e.g. 'product must be safe' or 'must not cause electromagnetic interference'). They are

[1] Conformity assessment: consists of checking the prototype and quality assurance measures along the series production process.
[2] Note from the Blue Guide: The term 'provision' does not refer to a product type, but to each individual product, regardless of whether it was manufactured as a single item or in series.
[3] The strictest technical clause is the state of the art in science and technology. The requirements profile is based on the latest technical and scientific findings. In contrast, the recognised rules of technology require compliance with what is generally scientifically recognised and practically proven.

developed by one, two or all three European standardisation organisations (CEN, CENELEC, ETSI) within the framework of this standardisation mandate. The manufacturer is generally obliged to carry out a risk analysis and assessment to ensure that the procedures used (hEN or alternative) address the essential requirements of the relevant legal acts and to document the results.[4] The application of these standards is fundamentally voluntary but serves as a 'technical basis' for the EU product regulations and facilitates proof of conformity.

If the references of harmonised standards under a directive or regulation are also published (also known colloquially as 'listed') in the Official Journal of the EU, these standards take on additional, decisive significance:

1. manufacturers who fully utilise such standards for conformity assessment benefit from the presumption of conformity. The market surveillance authorities must then assume that the product complies with the legal requirements (so-called *reverse onus,* aka the reversal of the burden of proof).
2. the choice of the applicable conformity assessment procedure, e.g. whether a notified body must be involved or not, depends for some legal acts on whether a listed hEN is applied by the manufacturer.

In the sense of the 'New Legislative Framework' (NLF), hENs form an essential basis for the placing on the market of safe products that comply with other protection objectives, such as electromagnetic compatibility or radio protection, on the internal market.

In this document, hEN refers to a harmonised European standard listed in the Official Journal.

2. Challenges due to missing or outdated hENs

If no hEN is available, the manufacturer can prove conformity by other means. The following two cases can apply:

- **Obsolete standards**, i.e. a listed hEN that no longer corresponds to the state of the art. The manufacturer should check whether additional measures are required.
- **No listed hEN available**: In this case, alternative methods are mandatory.

The standardisation regulation (EU) 1025/2012 stipulates that outdated hENs must be reviewed and, if necessary, revised on a regular basis. There are currently delays in the publication of new versions of standards and their listing in the Official Journal of the EU.

[4] Note from the Blue Guide: Even if the manufacturer uses a harmonised standard (the references of which have been published in the Official Journal and which addresses specific risks) to comply with the essential requirements, the risk assessment must be carried out and he must check whether the harmonised standard covers all the risks associated with the product.

3. Procedure in the case of missing or outdated hEN

Step 1: Identification of the requirements

The essential requirements of the relevant EU harmonisation directives and regulations must be analysed in detail. According to recital 11 of Decision (EU) No 768/2008/EC, these are formulated in such a way that it is possible to assess whether they have been complied with, even if harmonised standards are missing or the manufacturer has decided not to apply a harmonised standard. This allows for alternative technical solutions and verification methods to standards.

The manufacturer is generally obliged to carry out a risk analysis and assessment and to document the results. This is independent of the application of hENs. In addition to the intended use, the risk assessment must also include foreseeable misuse.

Step 2: Use of technical specifications

If no hEN is available, the following alternatives can be used, to determine the state of the art:

- Not listed EN
- International product standards (e.g. ISO, IEC)
- National product standards
- Industry-specific standards or company-specific technical specifications
- Own solutions, possibly supported by basic standards or product standards which cover similar or other products and product groups

According to Article 3 (2) of Decision 768/2008/EC, such alternative specifications may only be used if they fulfil the requirements of EU regulations. Documentation in the form of a comprehensive risk assessment is particularly important here in order to be able to prove conformity in the event of damage or during a market surveillance inspection.

Step 3: Possible involvement of a notified body

Even if the involvement of a notified body is not mandatory under the applicable EU harmonisation legislation, it may be useful in the absence of hENs.[5] According to Article 4 (5c) of Decision 768/2008/EC, notified bodies can carry out a conformity assessment specifically in such cases in order to confirm compliance with the essential requirements, e.g. a type examination certificate or a certificate of conformity.

[5] In part there is an obligation to integrate, e.g. Art. 3.2 and 3.3 RED

However, this generally increases the costs and extends the time required to prepare the conformity assessment. Therefore, this route should only be taken in absolutely necessary cases. Even if a third-party body was involved in the conformity assessment (voluntary or mandatory), full product responsibility remains with the manufacturer. This applies in particular to the obligation to issue an EU declaration of conformity under the sole responsibility of the manufacturer.

Step 4: Creation of technical documentation

The technical documentation serves as proof of conformity and must contain detailed information as required by the relevant EU legislation. The required minimum content of the technical documentation is specified in the respective conformity assessment procedures (see e.g. Annex II, 3. of Directive 2014/30/EU). This requirement must be fulfilled as a minimum. Section 4.3 of the Blue Guide (2022) recommends summarising the following components, among others:

- Product description and design documents
- Risk analyses and results,
- Test results and technical specifications,
- Measures to ensure compliance with the essential requirements.

4. Dealing with obsolete hEN

If a hEN is listed in the EU Official Journal but no longer reflects the state of the art, the Blue Guide (section 4.1.2.2) recommends that manufacturers:

1. check that the standard is up-to-date,
2. carry out additional technical assessments (incl. GAP analysis),
3. use alternative available specifications to minimise risks and demonstrate compliance.

If a newer version of the standard already listed is available but has not yet been published in the Official Journal, it must be checked whether it describes a higher state of the art (e.g. additional safety requirements, tests). If this is the case, then this newer state of the art should also be applied. Although a product can also be placed on the market in accordance with the (old) state of the art with a presumption of conformity, the product then only fulfils an outdated state of the art and not the current state of the art. In the event of damage (e.g. product safety incident), this presents the manufacturer with the challenge of proving that, despite the outdated state of the art, their product was not the cause of the damage.

Therefore, it is recommended to:

a) Make use of hENs listed in the Official Journal of the EU | **Effect**:
   - Manufacturer benefits from the presumption of conformity

b) Additional application of the current state of the art described in a more recent edition of the standard | **Effect**:

    - actual conformity with the protection objectives of a directive as described in the essential requirements
    - Improved legal position in the event of damage (safety) or in the event of alleged non-conformities with other protection

c) Indication of both listed and unlisted standards, including issue status, in the EU Declaration of Conformity | **Effect**:
    - Signal to customers and market surveillance: current state of the art is complied with

This procedure ensures that the presumption of conformity is maintained and, at the same time, the current state of the art is adhered to.

5. Procedure for hENs listed with restrictions

Restrictions are limitations that the Commission can impose when listing an hEN. They often lead to the loss of the presumption of conformity. One example is EN 302 194-2, which is listed with restrictions in the OJEU under the Radio Equipment Directive (2014/53 EU - RED). Due to the restriction, it does not trigger a presumption of conformity for the radio requirements for receivers.

Procedure for hEN restrictions:

1) Check whether the restriction relates to the specific product, as there are restrictions that only relate to certain classes of products.
2) Check the effect of the restriction on the presumption of conformity of the hEN.
3) Verify whether a restriction means that a notified body must be involved in the conformity assessment.
    a. No: Description of the application of the hENs listed with restriction in the risk assessment.
    b. Yes: Involve a notified body

6. Long-term strategies

- **Monitoring the standardisation landscape:** companies should actively monitor developments in the creation of new hENs and amendments to existing standards.
- **Participation in standardisation committees:** Active participation in standardisation processes offers the opportunity to contribute your own proposals and to receive up-to-date information on upcoming changes to standards at an early stage.

Conclusion

Even without available or current hENs, there are ways and solutions to ensure compliance with EU regulations. In principle, according to the NLF, the application of harmonised and listed standards is voluntary; the only legally binding requirements

are the essential requirements specified in the respective legal act and relevant to the product. The risk analysis forms the basis for the proof of conformity.

Whether the identified risks of the product are carried out with the aid of hEN or alternatively other technical specifications remains the responsibility of the manufacturer. Monitoring the development of standardisation helps to remain competitive and legally compliant in the long term.

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Bitkom e.V.
Albrechtstr. 10 | 10117 Berlin

Contact Person
Dr. Jacob L. Gorenflos López | Policy Officer Industry 4.0 & Technical Regulation
T +49 30 27576-269 | j.gorenfloslopez@bitkom.org

Responsible Bitkom Committee
AK Produktsicherheit und Marktzugang