Guidelines for hENs under the CPR

GROW C1 and CCMC - 28/06/2018

This document is an attempt to contribute to clarifying and agreeing on a common approach, in order to ultimately develop a template/guidance document for hENs under the CPR. It should thus serve as a guide for further work in developing such guidance/template, to be then used by TCs in their daily standardisation work. This document lays out the Commission view on how to arrive to an acceptable structure and content of a hEN under the CPR and presents the basis for further discussion in close collaboration with CCMC.

Some general principles for developing hENs under the CPR:

- The hEN shall harmonise "as little as possible and as much as necessary".
- The hEN shall be as short and simple as possible and be written in plain language that can be understood by all relevant stakeholders, even if they have not been involved in all stages of the development of the hEN, such as companies and market surveillance authorities.
- Any hEN clauses conflicting with the applicable rules set in or by means of the CPR shall be avoided.
- The hEN shall enhance the free movement of goods in the internal market. It is expected to boost competition and competitiveness in the industry.
- It shall provide clear information on how to declare the performance of a product – NOT arriving to a "judgment" (e.g. "fit for intended use").
- The hEN shall make life for market entrants, SMEs and micro-enterprises as easy as possible. This entails, firstly, the necessity to ensure fair and equitable participation of all stakeholders, including SMEs and micro-enterprises, in the standardisation process, so as to achieve the necessary inclusiveness.
- Secondly, the opinions of market entrants, SMEs and micro-enterprises, presented during the development process of the hEN, shall also be appropriately taken on board, so as to ensure the adequacy of the final outcome also from the point of view of these stakeholders.
- Rules defining when the performance in relation to given essential characteristics is to be declared cannot be contained in hENs as this is comprehensively regulated by the CPR.
- All performance-related characteristics of a product having an impact on any of the BWRs need to be addressed as essential characteristics in hENs, provided that they have a sufficient base in the mandating documentation (the respective mandate to CEN and the CEN answer to that mandate).
- For essential characteristics, references to national requirements as sources of obligations or assessment methods have to be avoided.
- Scope definitions have to be clear and unambiguous.
- Content of hENs following the CPD approach (outdated concepts, wording, etc.) is no longer allowed, both for new or revised hENs.
- Old Annexes ZA are no longer allowed, both for new or revised hENs. Any hEN will have to be reviewed and validated by the relevant consultant before this hEN is sent to the Commission

Commented [AG1]: Need to improve processes for classes and thresholds. This is also needs a change in how to approach a European Standard.
COM: agreed but does not belong to this guideline document.

Commented [AG2]: Up to know mandate is the basis. If mandates are updated this should not be a problem.
This contradicts the vademecum on European Standardization Standardization part 3
COM: agreed, text was added from the doc SCC 13/12

Commented [AG3]: We need to create a common position on how to approach this and DS.
COM: agreed, this text follows our subsequent discussions
In certain cases we may not consensus in one method and there is an essential characteristic for which we will not be able to provide a method. This should not be a reason not to cite a hEN. *COM: we could refer here to doc 13/12 expressing the 'flexible approach'*

Commented [AG4]: It is important to clarify the criteria for accepting new characteristics, e.g. technical relevance, availability of method. *COM: these are general principles only. While this would be useful to have, we do not think it belongs in this document about writing standards.*

for citation. The hEN will have to be accompanied by the consultant's recent written opinion, concerning the exact version of the EN that passed CEN final validation (BT).

- All links to internet pages referenced in the hEN must be tested and must work.
- Concepts such as 'class', 'classification', 'level' or other terms that have a very specific meaning under the CPR (notably have been contained in Article 2 definitions) shall be used in hENs in the same meaning as the one in the CPR.

Commented [AG5]: This may be a challenging. At the moment other concepts such as grades, categories are used to express performance. This can also have implications in the market. *COM: unfortunately, here we can't show flexibility from the explicit concepts of the CPR, but we acknowledge potential difficulties.*

Sections of the hEN

European Foreword

Commented [AG6]: CEN/CLC Internal regulations define what to be included in the foreword. *COM: sure, but for now, this is a COM guideline about what we think is useful and not in a hEN under the CPR.* Agreed that CCMC provides the template for this foreword.

GOOD PRACTICE:

- Mention who (which TC) prepared it.
- Explain which previous EN it supersedes.
- Summarise how it has been revised (which are the changes compared with the previous version); this goes in particular for changes of scope.
- Include the listing of all other relevant standards (where relevant, and rather in the Introduction part).
- Ensure that the foreword is coherent with text of the standard.
- The foreword informs whether there is an Annex ZA or other and if it is linked to a regulation/directive (but not specifically).

TO BE AVOIDED:

- This section of the hEN shall not refer to topics which have not been included in the main text of the hEN.

Scope

GOOD PRACTICE:

- Scope definitions have to be clear and unambiguous. It must be clear which products are covered by the hEN and which are not.
- If the scope definition is based on distinctions by intended uses, the outcomes of these distinctions shall provide a clear and unambiguous answer to the question, whether a given product is covered by the hEN (included in its scope).
- The hEN shall remain coherent with the accepted answer to the mandate and the work programme accepted by the COM.

Commented [AG7]: This item is not coherent with the point above on the link with BWR.
COM: cf. general principles above and our agreement reflected in SCC 13/12
GA: OK
The scope of the standard can include elements not covered by the mandate and the relevant ones will be reflected in Annex ZA.COM: OK but to be discussed in casu.

TO BE AVOIDED:

- The scope of the standard shall not exclude products or performance aspects included in Annex ZA.The hEN shall not exclude products which are already legally on the internal market, also during a revision of a hEN.

- The clauses on the scope shall not contain dynamic elements, i.e. rules about how to change the scope during the validity of the hEN, since inclusion of such elements would render the scope ambiguous at any given moment.

Normative references

GOOD PRACTICE:

The EN shall make all relevant cross-references to other linked (h)ENs. Legislation or parts thereof shall only be referred to (not quoted).

Terms, definitions and abbreviations

- Concepts such as 'class', 'classification', 'level', or other terms that have a very specific meaning under the CPR (notably have been contained in Article 2 definitions) shall be used in hENs in the same meaning as the one in the CPR.

Characteristics

GOOD PRACTICE:

- The hEN shall contain all the essential characteristics and proxies[1] included in the answer to the mandate accepted by the Commission.
- All performance -related characteristics having an impact on any of the BWRs need to be addressed as essential characteristics in hENs, provided that they have a sufficient base in the mandating documentation (the respective mandate to CEN and the CEN answer to that mandate).
- As mutually agreed between CEN and EC, this section shall contain for each essential characteristic and proxy a clear reference to the relevant assessment method to be used for the related performance (see also: Annex ZA). If no assessment method is available the inclusion of the characteristic should be delayed until the method is developed.
- Threshold levels or classes existing in hENs already cited in OJEU are to be transferred into a revised version of the standard without any modification, unless requested to be changed.
- When adding any new threshold levels or classes into hENs (or removing any existing ones), the guidance developed under the JIS Action 5 and given in "*Instructions for CEN how to propose classes and / or threshold levels in candidate or revised hENs* " shall be followed.

TO BE AVOIDED:

Commented [AG8]: As noted above we use terms as grades, categories not necessarily in the same way.
COM: cf above under general principles

Commented [LK9]: *'Essential characteristics' preferred by the COM, and 'product characteristic's preferred by CEN/CLC*

Commented [AG10]: Create overview of examples using proxies and have a discussion on they are used today and how they should be used
COM: agreed, ongoing

Commented [AG11]: How to deal with aspects to which we do not have a method? If we base our work in consensus, we may not agree on a method.
COM: agreed in principle (see suggestion in text)
GA: See general principles comment on how to include new characteristics. COM: OK, to be dealt with in casu

Commented [LK12]: To be reconsidered by the COM

Commented [AG13]: We need to conclude this guidance and process in Action 5
COM: agreed

[1] The concept of essential characteristics is defined in the CPR (cf. Article 2(4). The hENs frequently contain sub-items under their essential characteristics, and these sub-items are conventionally called proxies. Their purpose is to provide more precise indicators related to the performance of the product while still remaining within the essential characteristic in question. Owing to the provisions of Article 6, the manufacturer is to choose the essential characteristics, in relation to which he wishes to declare the performance of the product: on the contrary, under a given essential characteristic the manufacturer does not have the same freedom, but instead has to follow the clauses included in the hEN when having chosen to declare this essential characteristic. This could notably entail the obligation to declare the assessment results (the performance) of the product in relation to all the proxies under this essential characteristic.

- This section shall no longer (any future revisions of hENs) contain the terms 'Requirements', 'Product requirements' or 'product obligations'.
- The EN shall not define whether a performance in relation to given essential characteristics needs to be declared.
- For essential characteristics, references to national requirements as sources of obligations or assessment methods shall be avoided.
- This section should not include requirements on the materials/components to be used in a construction product.
- Avoid phrases such as: "the manufacturer shall declare / results shall be declared", "when required", "when demanded in the place of [final] use", "the value shall not be less/greater than…"; "shall conform to/meet the requirements…", etc.

Assessment methods

GOOD PRACTICE:

- Where possible, the hEN shall provide for assessment methods less onerous than testing, also to make the life of market entrants, SMEs and micro-enterprises as easy as possible.
- For each essential characteristic and proxy the hEN shall refer to only one assessment method. If more than one assessment method is given for the determination of the performance in relation to the same characteristic or proxy, it can be accepted if a correlation between them exists or can be developed, also to be included in the hEN. The hEN shall then select one of them as the method of reference.
- Assessment methods included in the hEN shall be directly related to the relevant characteristic or proxy.
- The hEN shall clearly indicate, for each essential characteristic and proxy, how the performance shall be expressed (e.g. units,…).

TO BE AVOIDED:

- Do not introduce any classes or threshold levels (incl. pass / fail criteria) in this section without following the instructions above.
- Avoid phrasing such as: "the value shall not be less/greater than…"; "shall conform to/meet the requirements…", etc.
- This section shall not contain the terms 'Requirements', 'Product requirements' or 'product obligations'.
- Reference to assessment methods for characteristics not required by the answer to the mandate accepted by the Commission.

Commented [AG14]: Need to discuss long term and short term approach
COM: agreed, discussion ongoing

Commented [LK15]: In a few exceptions (such as with kits only), this should be decided upon in casu

Commented [LK16]: When the manufacturer decides to test and declare, of course they need to declare the results. It needs to be clear how the assessment is to be carried out and results are declared.

Commented [AG17]: This is not always the case and in some instances there was a compromise with the EC endorsement.
In addition we should inform all stakeholders that more than one method can be used when agreed. If this is not possible today, the EC should correct all mandates as this is included in most of them.
COM: needs to be discussed further, but at a point in time we would like to cease these practices. For very few cases, to be assessed in casu if this principle can be applied.

GA: in a few cases tabulated values can be a 2nd possibility and or you could have alternative evaluation methods to testing .
COM: Noted, to be considered in casu.

Commented [AG18]: For dangerous substances this is not yet clear? Should we not refer to the method as long as the outcome of the performances should not be clear.*COM: OK.*

Commented [AG19]: GA: With the exceptions of thresholds provisions. *COM: agreed*

Commented [AG20]: Same as above.
COM: see above

Assessment and Verification of Constancy of Performance (AVCP)

GOOD PRACTICE:

- This section shall be as short as possible.
- The hEN shall contain clauses setting out how the constancy of the declared performance related to essential characteristics and proxies is kept under control and verified.
- The hEN shall specify the rules on factory production control, including where applicable those for micro-enterprises, as established in Annex V to the CPR and in the relevant Commission Decision setting the AVCP systems.
- The hEN shall specify the tasks of manufacturers and, where applicable, notified bodies in the AVCP context in the Annex ZA.

TO BE AVOIDED:

- The hEN shall not contain any variation relating to the intervention of a third party (e.g. for certification of constancy of performance).
- The hEN shall not contain normative references to quality management system requirements (e.g. EN ISO 9001, 14000 or related series standards) or certification provisions related to it.
- The hEN shall not contain rules on sharing or cascading, already exhaustively regulated in Article 36 of the CPR.

Commented [AG21]: This matter should be discussed bilaterally. The AVCP guidance is in the current form as this is required by the CPR and was based on previous agreement.
COM: correct, specific discussions needed

Classification

This section is not considered useful in a hEN under the CPR. It also creates confusion with the meaning of 'classes' under the CPR.

Commented [AG22]: This refers to classification of product in general and not of the performances.
COM: if this is about 'types of products', this title is misleading and would need to be reconsidered for all hENs under the CPR
GA: We will correct this in the Model standard.COM: Thank you

Marking, labelling and packaging

This section is not considered useful in a hEN under the CPR. Its content also creates confusion with the CE marking rules in the CPR and the instructions in Annex ZA.

Commented [AG23]: Marking is used in non-EU members or other matters outside DOP and CE marking. This is often used for designation code. It will be important for non-EU members.
COM: If this section is maintained it must be very clearly stated under it that it applies to certain cases only and that marking and labelling discussed there should not be confused with the DoP and the CE marking under the CPR.
Ok. COM: Thank you, exact phrasing to be agreed upon

Annexes (other than Annex ZA)

GOOD PRACTICE:

- Coherence between the Annexes and the main part of the hEN shall be maintained.

TO BE AVOIDED:

- Annexes (normative or informative) shall not establish classes, pass /fail criteria or other threshold levels.

- They shall not contain elements that are normally part of the core of the hEN, unless they are further elaborations of test methods.

Commented [AG24]: This may be used for test methods as the Internal Regulations allow the inclusion of methods in Annexes for a better reading of the standard.
COM: agreed.

Annex ZA

GOOD PRACTICE:

- Use the new Annex ZA guidance document (Part I) and template (Part II) (TF N 687rev1 2015-06-02), the old template is not acceptable any more.
- Annex ZA shall contain all the essential characteristics and proxies included in the answer to the mandate accepted by the Commission, aligned with the content under section "Essential characteristics" (see above).
- Table ZA.1's essential characteristics must match the content of the main part of the hEN.
- For each essential characteristic and proxy Annex ZA shall contain a clear reference to the relevant clause including the assessment method to be used for the related performance.
- The presentation of the AVCP tasks shall cover all applicable AVCP systems, not only some of them, and shall be done as clearly as possible.
- The EN shall make all relevant cross-references to mandates.

Commented [AG25]: The mandates often limit the AVCP system and create false systems. Several hENs today follow the same approach.
COM: point taken .These will have to be improved. Foreseen in the mandate revision process.

TO BE AVOIDED:

- There shall not be fewer essential characteristics in Table ZA.1 than in the main part of the hEN, and not more in the main part than are in Annex ZA.
- There shall no longer be examples of DoP and CE marking in this document.
- There shall no longer be a table mentioning the AVCP system.
- There shall no longer be a clause on NPD.

Commented [LK26]: GA: The standard can contain other characteristics that are not harmonized. *COM: As discussed, the treatment of additional characteristics is to be solved in the medium term by including them in the mandates over time and in the short term by ad hoc solution such as exclusion notes in Annex ZA.*

Annex

For information only

Main reasons for rejection of hENs by the Commission in order of frequency (based on approx. 200 analysed hENs between 2014-2017):

1. New / modified classes and thresholds without having followed the adequate procedure
2. Additional requirements outside Annex ZA (& voluntary marks)
3. New / Missing / different ECs in Annex ZA vs Mandate
4. Inappropriate wording / errors mostly related to the old CPD terminology
5. Issues in the AVCP and FPC sections
6. Introduction of pass/fail criteria
7. Scope issues, faulty dangerous substances clause, Member State opposition to citation