CEN-CENELEC Sector Forum on PPE
N 333

CEN-CENELEC
Sector Forum on PPE

EUROPEAN COMMITTEE FOR STANDARDISATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

DIN Deutsches Institut für Normung e. V. · 10772 Berlin

To the members of the
CEN-CENELEC Sector Forum on PPE

Your reference	Our reference	☎ +49 30	Berlin
	sha	2601-2024	2017-06-30

Approach for dealing with hazardous substances in standards for PPE

Dear Sir or Madam,

Enclosed you will find the document “Approach for dealing with hazardous substances in standards for PPE”, which was developed by Dr. Michael Thierbach. The aim is to publish the document by the SF as guideline for standard writers, e.g. on the CEN-CENELEC website.

We kindly ask you to comment the draft by the end of the year, after consultation with “your” TC and WG members, so that a next draft can be ready for the next SF meeting.

Please submit your comments to Dr. Thierbach (Thierbach@kan.de) by **2017-12-31 at the latest**.

Thank you in advance.

Yours sincerely

DIN Personal Protective Equipment Standards Committee (NPS)

Andreas Schleifer
Secretary of PPE Sector Forum

SECRETARIAT DIN
DEUTSCHES INSTITUT FÜR NORMUNG e.V.
[redacted]
mailing address: 10772 Berlin
(for visitors: Am DIN-Platz Burggrafenstr. 6, 10787 Berlin)
Fax: + 49 30 26 01-42024·email: Andreas.Schleifer@din.de

An approach for dealing with hazardous substances in standards for PPE

draft for the PPE Sector Forum
version 12 June 2017

The topic of "innocuousness" is of growing relevance in PPE standardization. The aim of this document is to provide a coherent approach in order to face the complexity of the issue. It is not aiming at imposing any obligation on TCs for setting limit values but at assisting them whenever they decide to do so.

1. Regulation (EU) 2016/425 on PPE

- Specifically Annex II, Section 1.2, requires that PPE must not create inherent risks or other nuisance factors
- In particular, the materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users

2. Basics for standards requirements

- The European Single Market as well as European workplace regulations not only assure fair market conditions, but also have the objective of assuring protection against health hazards by *preventing them at source*
- In order for a high level of user safety and health to be assured, as required in the regulation, exposure of wearers of PPE to substances harmful to health should be *prevented wherever possible*
- Taking into account that certain substances are needed to assure the performance required by the PPE, materials that at some stage release substances that could be toxic, carcinogenic, mutagenic, allergenic or teratogenic *should be avoided even in the manufacturing process* of PPE
- In this context, manufacturers must not merely consider technical and economic aspects: the *state of the art and good practice at the time of design and manufacture* are crucial[1]
- PPE *exhibiting avoidable concentrations* of a hazardous substance, for example because they have not been treated adequately (e.g. washed) during the manufacturing process, may also contain higher concentrations of other production residues that *present additional hazards*

3. CEN Guide for addressing chemicals in standards

- Establishing standards provisions on chemicals is a complex task requiring specific knowledge
- CEN Guide xy:2017 provides very helpful *guidance on addressing chemicals in the development of standards for consumer-relevant articles*
- However, it is *very useful also for non-consumer-relevant PPE* because, inter alia, it helps to
  - identify and understand basic principles that need to be considered
  - identify and understand the regulatory (e.g. REACH, CLP) and political background as well as existing voluntary initiatives and tools relevant to chemicals in articles/products

4. Role of REACH in order to determine the state of the art for products

- First of all, see CEN Guide xy:2017 for many details on REACH
- Put very simply
  - Chemicals must be registered under REACH as soon as a certain quantity threshold is exceeded when a substance is manufactured and placed on the market
  - Substances in articles such as PPE are required to be registered only if they are likely to be released during normal or reasonably foreseeable use
  - In addition, authorization procedures exist for substances of particular concern
- *Annex XVII of the REACH Regulation* governs the manufacture, placing on the market and use of *certain dangerous substances*, mixtures and articles; *examples* relevant to PPE are restrictions for
  - Chromium (VI) in leather able to come into contact with the skin

[1] Regulation (EU 2016/425), Annex II, Preliminary Remark 3

  - Azodyes which may release certain amines in leather or textile articles which may come into direct and prolonged contact with the human skin or oral cavity
  - Nickel in parts of items of clothing that come into direct and prolonged contact with the skin

  Where such dangerous substances have already been evaluated and included into Annex XVII, it is generally correct for the limits specified in Annex XVII of the REACH Regulation (and which are frequently based upon the detection limits) also to be adopted in product standards for PPE
- For substances included only on the *list of candidates for substances of high concern* (for which authorization under REACH is an objective) the availability of suitable alternative substances or technologies is examined for each application
  - This evaluation, which has not yet been completed, must be considered for product manufacturing methods, and is also relevant to product safety standards
- In Article 33 of the REACH Regulation a *threshold for the duty to communicate information* of 0.1% by weight is stipulated
  - It is not possible for this threshold for the duty to communicate information in REACH to be used to formulate a concentration of the substance in a PPE at which the substance can be classified as being innocuous when this PPE is used – irrespective of whether a substance is subject to mandatory registration, restriction or authorization under REACH

5. Role of occupational exposure limits or DNELs[2] in order to determine the state of the art for products

- Exposure to *inhalable* substances in the atmosphere must be distinguished by exposure to substances absorbed by the user *through the skin*
- An occupational exposure limit for a hazardous substance is *intended for workplaces* at which contact with the hazardous substance *cannot be avoided* because it is required for the *production process* concerned, and *not intended* as a product characteristic
- The *teratogenic effect is sometimes not covered* by occupational exposure limits. It must be assumed in this context that:
  - Pregnant women are often not immediately aware that they are pregnant and consequently are not able to inform their employers of the fact in time for the latter to take the necessary measures
  - Many users of PPE are smaller businesses or companies without adequate in-house expertise in hazardous substances, and are consequently not even aware that PPE may contain teratogenic substances that they are obliged to protect their pregnant employees against

6. Resulting recommendations for drafting standards requirements

- Specify requirements on hazardous substances in order to reduce exposure of the user *to the minimum possible*
- Where *attainable by the state of the art*, avoid the release from PPE of substances that could have a harmful effect upon the wearer of the PPE, irrespective of the toxicological rationale of limit value scenarios
- Do not justify *avoidable levels* of hazardous substances in PPE neither with occupational exposure limits, nor with possible alternatives such as derived no-effect levels (DNELs)
- Do *not use the threshold for the duty to communicate information in REACH* to define a concentration at which a substance can be classified as being innocuous in PPE
- In general, where a dangerous substance has already been evaluated and included into Annex XVII of the REACH Regulation, you can refer to the limit specified in Annex XVII (and which are frequently based upon the detection limits) also in product standards for PPE

[2] DNELs are "derived no-effect levels" under the REACH Regulation which human beings should not be subjected to exposure