



An approach for dealing with hazardous substances in standards for PPE

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. However, TCs are encouraged to include normative provisions addressing chemicals in PPE, if relevant for the respective standardised product.

1. Regulation (EU) 2016/425 on PPE

- *Annex II, Section 1.2.1, requires that PPE must not create inherent risks or other nuisance factors*
- *In particular, section 1.2.1.1 requires that 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*
- *According to Annex II, preliminary remark 3., the essential health and safety requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture, as well as technical and economic considerations which are consistent with a high degree of health and safety protection*

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*
- *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 as far as possible*
- *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 crucial¹*
- *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*

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

3. CEN Guide for addressing chemicals in standards

- *Establishing standards provisions on chemicals is a complex task requiring specific knowledge*
- *CEN Guide 16:2017 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 16:2017 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*
 - *Azodyes which may release certain amines in leather or textile articles which may come into direct and prolonged contact with the human skin*
 - *Nickel in parts of items of clothing that come into direct and prolonged contact with the skin²*
 - *Cadmium and its compounds (used in pigments e.g. to colour plastics)*

Some of such dangerous substances have already been evaluated and included into Annex XVII; in these cases product standards for the conformity assessment of PPE should not deviate from these legally binding limits specified in Annex XVII of the REACH Regulation (and which are frequently based upon the detection limits) Test methods for determining content or release of these and other substances are available in European and international standards
- *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*

² In the context of PPE it should be noted that nickel is also relevant for spectacle frames

- *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 DNELs³ 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, do not deviate from the limit specified in Annex XVII (and which are frequently based upon the detection limits) also in product standards for PPE*

³ DNELs are "derived no-effect levels" under the REACH Regulation which human beings should not be subjected to exposure