Minority opinion of the German Competent Authority (CA) regarding the Union authorisation application for a product family containing CMIT/MIT discussed at BPC-37

The German CA raised concerns in respect of the applicability and enforceability of the risk mitigation measures for treated articles as ongoing discussions between the Member States and pending decisions of the Commission should be taken into account before adopting the opinion on this application. Moreover, the German CA questions if risk mitigation measures for articles treated with treated articles are in the scope of the Regulation (EU) 528/2012 (BPR) at all and can be laid down in the authorisation.

In addition, the German CA noted that for some articles treated with the biocidal product, distribution to the general public cannot be excluded. The German CA proposed to set a risk mitigation measure that biocidal products should not be used to treat articles that could be distributed to the general public. This is also in line with the respective condition laid down in the active substance approval, which is related to the skin sensitizing properties of the active substance. However, the BPC did not agree with this proposal. The measure included in the application instead is of general nature, not taking into account that wearing of personal protective equipment is no option to mitigate a risk for the general public. According to the view of the German CA, this measure is not appropriate to protect the general public.