Státní zdravotní ústav

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Minority opinion on the application for the renewal of Propiconazole for PT 8

10 March 2022 - CZCA

The BPC meeting no. 42 adopted by majority the BPC opinion for renewal of the active substance Propiconazole. In this opinion as well as in the corresponding assessment report Propiconazole is claimed to be, an endocrine disrupting substance. The assessment report claims that the evaluation was performed, and the conclusion reached, in accordance with the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. However, even after the BPC discussion, it is still not explained how Propiconazole fulfils the definition of endocrine disruptor provided in the cited guidance. According to the guidance for a substance to be considered an endocrine disruptor an adverse effect linked to its ED modality must be observed. The adverse effect is defined as a change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase insusceptibility to other influences. It is the second half of the definition that has not been yet explained. No impairment of functional capacity resulting from either of the two effects (increased AGD, temporary variation in oestrous cycle in early age) has been specified. Instead, arguments were provided why the definition does not have to be fulfilled. One of these arguments that the guidance is not legally binding may be true, but contradicts the long term practice where abidance by guidance documents has been consistently required. Furthermore, as mentioned above, the assessment report claims that ED potential was evaluated according to the guidance. Another argument claimed that the definition of adversity is made partly obsolete by the following text in the guidance: „the definition of adversity is generic and not specific to the endocrine assessment and current practices are applicable for deciding whether the observed effects are treatment-related and should be considered adverse“ However, it was not explained how this negates the definition or why the authors did not change the definition instead of trying to partly negate it by an additional text. It was argued that deciding what constitutes adverse effect is up to the HHWG which does not have to take the above definition into account. In our opinion, such approach is in contradiction with common legal practice. A purpose of clear definitions in legislation is a need for safeguards against arbitrariness. Thus, definitions in legislation ensure predictability and legal certainty. We acknowledge that some legal texts do not, often purposefully, define certain terms, leaving it to the courts to decide what falls and what does not under such term. A definition may appear later from the judiciary practice. This, however, is obviously not the case here. In the guidance a clear definition of adversity is provided. This definition is a safeguard against arbitrariness and must be taken into account in the evaluation of ED potential of substances falling into the legal framework under the BPR. A different approach, such as the one advocated by the proponents of the majority opinion, results in legal confusion and uncertainty. This than undermines the validity of the approval process as a whole.

Conclusion: Under the BPR Propiconazole cannot be currently considered an endocrine disruptor. The text of the BPC opinion and the AR should be modified correspondingly.