FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu
Directoraat-generaal Leefmilieu
EUROSTATION – Bloc II
Victor Hortaplein, 40 bus 15
B – 1060 BRUSSEL

18/12/2017

BPC-23: Minority opinion of the Belgian Competent Authority (BE CA) regarding the BPC Opinion on a request according to Article 38 of Regulation (EU) No 528/2012 on Questions on unresolved objections during the mutual recognition of two IR3535 containing insect repellents

The BE CA is of the opinion that at the moment of the submission of the dossiers, the two products were assessed in good faith. Since very limited, and no harmonized guidance was available at that time, the BE CA consequently followed the established methodology in the CAR of IR3535, with expert judgment used to consider the field trials as worst case justifying the use of other more realistic application rates during exposure assessment. In this way, a two-fold similar approach was followed as was already accepted in the past for other PT19 products now authorised: using the already agreed approach in the CAR of an approved active substance to fix the application rate (Boomsma and Parthasarathy, 1990), and acknowledging the resulting discrepancy in the same way as it was accepted for DEET products. Therefore, taking all these facts into consideration, the BE CA is of the opinion that the conditions of Article 19(1)(b)(i) and (iii) of the BPR can be considered as met.

As a consequence, the BE CA is of the opinion that a better way forward would have been to consider that the efficacy tests in the applications represent an unrealistic worst case scenario where an unrealistic dose rate was used, allowing for a similar approach as for the referrals of DEET containing products, requiring that any new agreed guidance developed in the future, addressing the discrepancy between the dose rate proven efficacious in efficacy tests and the dose rate used for the exposure assessment, should be used at the renewal stage of the products.

The BE CA also wants to stress one more time that there is urgent need for cooperation between efficacy experts and human health experts, to together tackle the discrepancy between efficacious dose and application rate. Only in this way the necessary new guidance can be developed in a way that it will serve its purpose.