

European Chemicals Agency
Erik van de Plassche
Helsinki
FINLAND

Biocide Coordination Unit

Subject: FR minority opinion on the Draft Opinion related to questions on unresolved objections during the mutual recognition of two IR3535 containing insect repellents (BPC-23)

Aurélie Chézeau/ Romy Collet
- Anses

Email:
Aurelie.chezeau@anses.fr
Romy.collet@anses.fr

As commented during the BPC-23, France cannot support the conclusions presented in the ECHA BPC Opinion related to questions on unresolved objections during the mutual recognition of two IR3535 containing insect repellents.

More specifically, FR CA agrees with point 1 and point 2 of the overall conclusions of the BPC opinion but does not support points 3 and 4 of these conclusions.

France agrees with ECHA BPC opinion that conditions of Article 19(1)(b) are not met.

France considers unacceptable the inconsistency between the efficacious dose and the dose used for the risk assessment, which leads to the consequence that no complete protection time (CPT) is determined for the products when used at the dose claimed.

France does not support the conclusion that there is no existing guidance at the EU on how to generate efficacy data for repellent products. France is of the opinion that EU efficacy guidance are available for repellent products. As described in the guidance, the doses to be tested should be adapted to support the claims of the products and ensure that a correct complete protection time is given in the SPC.

As the conclusions presented in the ECHA Draft Opinion were adopted by the BPC, France submits a minority opinion.

Yours Sincerely

Aurélie Chézeau
BPC core member for France