POSITION PAPER
21/05/2023 – POS/23/LO/36836

CropLife Europe position on the EFSA Guidance on the use of the benchmark dose approach in risk assessment

In October 2020, EFSA published its Guidance on the use of the benchmark dose approach in risk assessment. The document comes from the EFSA Scientific Committee and applies to different areas addressed by EFSA including the evaluation of dossier for active substances in Plant Protection Products (PPP).

CropLife Europe agrees on the value of benchmark dose (BMD) level analysis. However, we believe this approach is complex which involves a need to understand Bayesian statistical methods to conduct or review analyses, as well as having associated tools being fully transparent (no black box). In addition, the BMD approach is also known to be vulnerable to significant subjectivity differences between different experts. **Therefore, we believe several points need further development before such an approach is introduced into the EU PPP evaluation framework**, for example there are still significant problems with the tool which need to be fixed.

In addition, the view of the group of academic experts who have developed the guidance and its corresponding tool is clear that not all datasets are suitable for or benefit from BMD analysis. **We then see a risk in the premature use of BMD for endpoint derivation – as illustrated by the recent inclusion in the revised EFSA Birds and Mammals guidance document.**

Current OECD guideline studies are also not designed to support BMD analysis, **therefore there is a very real and frequent risk for standard data sets of generating very low limits of confidence**. This in turn will distort the real endpoints by orders of magnitude from the true values and result in adding substantial invisible and inappropriately high conservativeness to the risk assessments which will lead to potential increased vertebrate testing and animal welfare concerns. Conducting BMD analysis on unsuitable datasets from OECD guideline studies would result in assessors requiring expert knowledge and a deep dive into the data to distinguish what the scientifically true endpoint value and appropriate safety factor is and would complicate the decision making and communication process for most risk managers and of course the public.

On that basis, CropLife Europe calls for an open and transparent discussion between EFSA, Commission, Member States, Academics and Industry experts on how BMD-modelling could be introduced in the EU pesticide regulatory framework in a meaningful way.

CropLife Europe aisbl | 9 Rue Guimard | 1040 Brussels | Belgium | BE 0447 618 871 Register of Legal Persons
Francophone Section of the Business Court of Brussels | croplifeeurope@croplifeeurope.eu | www.croplifeeurope.eu
Tel: +32 2 663 15 50 | Fax: +32 2 663 15 60