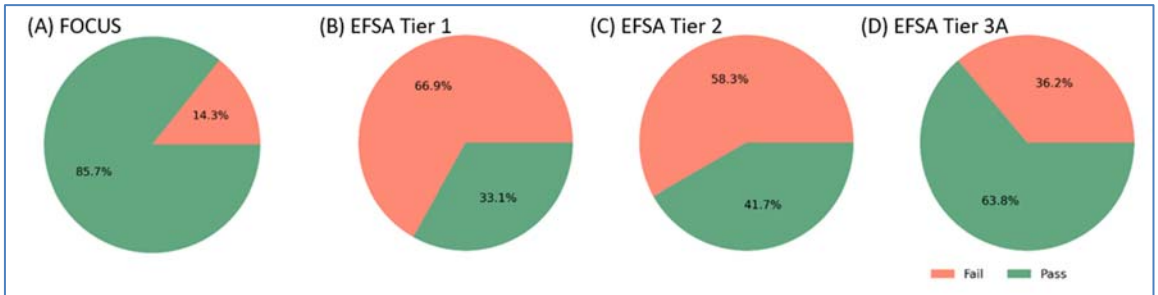
POSITION PAPER
03/03/2022 – POS/22/LO/35109

CropLife Europe position on the proposed new EFSA soil exposure modelling framework

- Current environmental risk assessments for plant protection products require comparison of a soil exposure estimate with an EU agreed ecotoxicological regulatory acceptable concentration (PEC_{SOIL}). The proposed new EFSA soil modelling framework includes three distinct tiers of exposure estimates, including new uncertainty factors in early tiers.
- **CLE has conducted an impact assessment with 56 active substances and 56 metabolites currently passing EU evaluations**. **These assessments now reveal a considerable increase of conservatism for PEC_{SOIL} values: up to x200 for Tier 1, x80 for Tier 2 and x34 for Tier 3.** These significant increases in predicted exposure **are driven primarily by non-validated assumptions on soil bulk density and the unrealistic simulation of product application during precipitation events**.
- A comparison of pass/fail rates in this reveals a **significantly higher rate of failure**:



Failure rate (%) of the ecotoxicological Tier 1 soil risk assessment based on exposure values calculated with FOCUS, 1997 (A) or EFSA, 2017 (B-D).

- **The increased rate of failure necessitates a higher degree of reliance upon higher tier field testing to resolve risk assessment**. It is noted that parallel ecotoxicology guidance to support coherent risk assessment procedures and confirmation of higher tier assessment options is not yet available to support these refinements which are now far more critical.
- Due to the high conservativeness of the new modelling, the uncertainty on how to use these values in a soil risk assessment scheme, and the demonstrated high failure rate of the risk assessment, **CLE recommends to the Commission, Member States and EFSA that further work should be conducted:**
    - **to allow further validation of the modelling methodology and scenario assumptions, and**
    - **to allow alignment of the tiered approach with the future soil organism guidance.**
- The proposed modelling framework in its current state will also lead to more resources needed from applicants and evaluating authorities to navigate through the uncertainty it creates, with a clear impact on innovation and delivery of new solutions to European farmers.

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