POSITION PAPER
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CropLife Europe position on the proposed new version of the EFSA Birds and Mammals Guidance Document

- **CropLife Europe supports a high level of protection for birds and mammals.**
- **The new version of the EFSA Birds and Mammals Guidance Document dramatically increases the complexity and number of assessment scenarios without defined links to a lack of conservatism in existing risk assessments.**
- **This will result in an immense workload and need for expertise in Member State authorities.**
- **CropLife Europe strongly recommends to the European Commission and to Member States not to endorse this new document before it has been further worked on, so it is fit for regulatory use.**

CropLife Europe supports a high level of protection for birds and mammals. However, we do not understand the unrealistic increase of complexity and conservatism in the new version of the guidance document published by EFSA. In our view this is not justified or supported by a demonstrated lack of protection for birds and mammals resulting from current evaluations, related protection levels agreed by risk managers, nor by any available monitoring data on wild birds or mammals poisoning incidents.

The risk assessment for birds and mammals uses a tiered approach to assess the risk of acute and reproductive effects. The new version does not change this approach but **dramatically increases the number of relevant assessment scenarios**, which results in a significant increase in the complexity of the risk assessment. This complexity is further increased by the proposed re-evaluation of relevant toxicity endpoints, as well as re-evaluation of exposure parameters. Conducting these re-evaluations is expected to have significant implications on resources for all stakeholders to assess the vast amount of additional information that needs to be provided. A high number of toxicological studies will need re-evaluation to justify the ecotoxicological relevance of any potential adverse effects and to recalculate the existing endpoints (BMD10s instead of NO(A)ELs).

Besides the increased complexity, as described above, the new guidance document is also significantly more conservative. CropLife Europe's impact analysis shows that according to the new requirements it may not be possible to demonstrate acceptable risk for many of the currently registered active ingredients and plant protection products based on the screening step and the Tier 1 step of the exposure assessment. **This will trigger the need to rely on higher tier refinements for which additional ecological / behavioural studies must be conducted**. Evaluation of these studies will further increase the workload of stakeholders, especially of evaluating authorities.

Moreover, for higher tier studies, the new methodological requirements, additional criteria and uncertainties in the interpretation of findings will trigger the need to repeat many of the existing studies, and to conduct a significant number of new field studies. Practical aspects of the study methods are still under discussion which currently makes it difficult to plan such studies that could be in line with the new guidance document. It must be considered that the design and execution of higher tier studies can take a significant amount of time, assuming that resources and expertise are available at the conducting Contract Research Organisations (CROs) to meet the new requirements. Furthermore, the conduct of higher tier field studies is normally season dependent and this means that sufficient time is needed to generate fit-for-purpose higher tier data packages. Finally, we want to note that the current version of the new guidance document does not provide clear guidance on how such studies should be evaluated. It is

therefore expected that this will result in non-harmonised evaluations by Member States. **Overall, the workload will dramatically increase for both the industry and the regulatory authorities and we believe that this additional resource demand is not justified considering the sufficient level of protection for birds and mammals already set in the EU.**

Finally, the calculator tool provided with the guidance document, while helpful in certain situations, suffers from a lack of transparency and still needs many improvements to efficiently facilitate evaluation processes. CropLife Europe is ready to support the software development effort as it seems that the tool was developed without sufficiently considering assessors' and applicants' practical needs. The release of the calculator's source code, as well as a traceability of updates to any future version, will further serve to increase its transparency.

In conclusion, the new Birds and Mammals Guidance in its current state is expected to result in significantly more complex risk assessments and consequently in a significantly higher need of resources for all stakeholders, especially evaluating authorities. Due to this increased complexity, CropLife Europe is concerned that evaluating authorities will face difficulties to meet official evaluation timelines. Additionally, a bottleneck is expected for delivering fit-for-purpose higher tier data packages, due to the season dependent character of higher tier field studies and capacities at CROs. Altogether, this will result in a clear impact on both registrant submissions and authority evaluations of dossiers, ultimately reducing innovation and delivery of new solutions to European farmers.

Considering the above, **CropLife Europe recommends to the European Commission and Member States to launch a concerted technical review by end users and develop an implementation roadmap for this document focused on:**

- **BMD analysis implementation,**
- **Clarification on how to perform higher tier studies that meet new expectations and sufficient time (a minimum of 30 months) to generate them,**
- **Fully transparent and fit for purpose calculator.**

CropLife Europe is willing to engage with EFSA, the European Commission and Member States to constantly improve assessments of pesticides and biopesticides. We remain prepared to contribute transparently to such an exercise, including by providing specific data. Experience from the pollinator topic showed how important it is to have a regulatory science driven document delivering clear guidance and not unnecessarily and unjustifiably adding on extra requirements.