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CropLife Europe input for SCOPAFF meeting 24-25 May 2023

- **Efficient use of IUCLID**
- **New scientific Guidance Documents and their cumulative impact**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 24-25 May 2023, CropLife Europe would like to provide input on several issues:

A.03 – Point 3 - IUCLID

We would like to reiterate our concerns when it comes to the implementation of IUCLID for active substances dossiers. While technical issues are still there, and we thank EFSA and ECHA for their continuous support and reactivity, **we still see a fundamental problem with new versions of IUCLID being automatically imposed on already submitted dossiers.**

This results in dossiers' content being altered automatically by the system, with content being shifted around due to new entry fields. We believe a duly and legally submitted dossier should not receive such alteration nor should it be the task of applicants to correct afterwards issues triggered by a forced migration. Contrary to the REACH framework for which IUCLID was developed, the PPP framework relies on legally binding timelines for applicants, limited abilities to amend a dossier once submitted and trust that information provided will be seen as intended by the evaluators. IUCLID is updated twice per year, and it is an unnecessary burden on applicants to correct dossiers twice a year. This will be especially impactful on applicants with limited resources such as SMEs.

We understand the technical limitations as IUCLID is controlled by ECHA development roadmap, nevertheless **we believe PPP authorities should be made aware and encourage that a proper life-cycle management should be developed for IUCLID, or at least in a forked version of IUCLID developed to fit the PPP framework principles**. CropLife Europe is ready to engage and discuss how such development could take place. Similarly to the IUCLID Integration Platform[1] CropLife Europe developed, we are ready to contribute with technical expertise and resources if it can facilitate pesticide and biopesticide dossier submissions and management.

A.07 – Guidance Documents and their cumulated impact

CropLife Europe would like to raise its high concerns on the unseen impact of new scientific guidance documents. We see several documents being published or draft versions of upcoming guidance which will have a clear impact on the evaluation process and on applicants' capacity to invest in new solutions in Europe, being conventional or biopesticides.

The following guidance can be used as example:

- New EFSA Guidance on the use of the benchmark dose approach in risk assessment

[1] https://esubmission.croplifeeurope.eu/iip/

- Revised EFSA Guidance Risk assessment for Birds and Mammals
- New EFSA soil exposure modelling framework
- Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water.
- EFSA Guidance Document on the risk assessment of plant protection products on bees (We are still analyzing this extensive document).

Please find in the annex to this letter CropLife Europe positions and impact assessment documents on this guidance. All have in common to step out of properly calibrated tiered approaches, with drastically increased conservative in the first tier, leading more substances into higher tier – if the options are even doable – which will require extensive resources for generation of data and for analysis by national evaluators. They also raise the complexity level of assessments to unseen levels without in the end providing the practicality which should be expected from fit for purpose guidance documents.

We fear the accumulation of impacts on Member States and applicants' resources to cope with all these new documents is not perceived. We welcome the prioritization exercise on guidance documents initiated by the Commission, but this will not address the uncontrolled rush towards increased complexity, resource incentive and unjustified conservatism we see in their development.

We would recommend for risk managers to explore measures to ensure scientific and technical guidance documents are fit for end users, such as:

- **Ensuring all Member States are involved in the initial framing and first commenting of a new document.**
- **Requesting the development of realistic case studies – already at the draft version stage.**
- **Requesting that any new guidance should be provided with a section estimating its practical applicability and possible impact on Member States/applicants resources.**
- **Setting up testing phases with the transparent support of applicants.**
- **Designing pilot projects led by RMS and opened to willing applicants.**

CropLife Europe and its members are willing to support any efforts actively and transparently if this can enhance the applicability of these documents and ensure they provide increased practicality, certainty, and predictability of the evaluation process.

We believe these documents have much more impact overall on pesticides and biopesticides dossiers and further control is urgently needed if we want to deliver efficient new solutions to support a more sustainable crop protection in the EU.

Yours sincerely

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cc. Almut Bitterhof
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Manuela Tiramani

This letter will be published on the CropLife Europe website and will be available at:
https://croplifeeurope.eu/resources-library/

In Annexes to this letter:

- *Annex 1 - CropLife Europe position on the proposed new EFSA soil exposure modelling framework*
- *Annex 2 - CropLife Europe Impact assessment report on the new PEC soil exposure modelling framework*
- *Annex 3 - CropLife Europe position on the new EFSA Birds and Mammals Guidance Document*
- *Annex 4 - CropLife Europe position on the draft Water Treatment Guidance May 2023*
- *Annex 5 - CropLife Europe proposal Tox testing scheme.*
- *Annex 6 - CropLife Europe position on the EFSA Guidance on the use of the benchmark dose approach in risk assessment*