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## CropLife Europe input for SCOPAFF meeting 19-20 May 2021

- **Guidance document on relevance of metabolites in groundwater**
- **Improving the efficiency of the process of a.s. approval / renewal**
- **Illegal plant protection product use**
- **New Transparency rules: General Food Law amendment and implementation**
- **Revision of the EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 19-20 May 2021, CropLife Europe would like to provide input on several issues:

### **Guidance document on the assessment of the relevance of metabolites in groundwater (A.07)**

CropLife Europe welcomes the planned adaptation of this important guidance to technical progress, that will reflect recent developments in genotoxicity testing and other areas of the environmental relevance assessment. However, we would like to highlight the need for an appropriate date of application. Indeed, it takes approximately one year to develop the non-relevance dataset for a metabolite. Also, such data are usually submitted to support community reviews and are evaluated by EFSA several years after submission. It is therefore critical that **a suitable transition period is adopted, and that the new requirements do not apply to active substances under evaluation.**

### **Improving the efficiency of the process of a.s. approval / renewal (A.12)**

We would like to raise again the issue of the lack of assessment capacity at the competent authorities level in many Member States. The issue is today becoming much more acute with consequences on innovative solutions being prevented to enter the process. This is the case for new EU level submissions but also for other regulatory actions at Zonal and Member States level. The causes have been clearly identified in the Commission REFIT report. **In order to address that recurrent problem, we would invite the Commission to consider a discussion in a dedicated forum, similar to what was done on Zonal issues back in June 2015 (Dublin workshop).**

We believe possible solutions can be discussed in a forum where applicants, Member States, EFSA and Commission could exchange, and ensure the EU pesticide regulatory system is improved and further contributes to the objectives of the Green Deal and the Farm to Fork policy.

### **Illegal plant protection product use (A.16)**

CropLife Europe welcomes the continuous efforts made by the Commission and the Member States against illegal plant protection products. Nevertheless, practical cases of misuse of the EU rules on parallel trade have been common for many years to put illegal products on the EU market (referenced in DG SANCO report<sup>1</sup>). **We believe a targeted update of the Guidance Document for parallel trade would improve effective control and sustainable use of PPPs.** CropLife Europe suggests a specific dialogue with the Commission and interested Member States can be put in place so concrete update proposals can be explored.

<sup>1</sup> [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_ppp\\_illegal-ppps-study.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_illegal-ppps-study.pdf)

### New Transparency rules: General Food Law amendment and implementation

The new transparency regulation is now applicable since nearly 2 months and we would like to thank EFSA for the extensive work and responsiveness of their helpdesk staff to answer practical questions. Several IT elements which were not fully operational in April have now been corrected or about to be fixed in the very short term. Nevertheless, we would ask from the Commission and/or EFSA, a **formal acknowledgement these temporary issues created impossibilities for applicants to properly meet their legal obligations**. We fear that years later, when actual submissions containing notified studies will be made, no recollection will be available of these delays – potentially leading to mismatches with severe consequences for applicants under the new rules.

We also would like to raise the current difficulties for applicants in getting pre submission advice virtual meetings organised. For such requests an EFSA interface must be used (no more than twice), which limits the description of issues to 100 characters each and no possibility to attach anything. This makes the service completely inoperable. **We would call for such limitations to be lifted**. Coordination between EFSA and RMSs is essential and not having the possibility of an **actual dialogue** so as to better prepare upcoming submissions can lead to further delays and constraints on evaluating authorities resources. Written exchange are not sufficient to address complex topics in a timely manner, and we would call on EFSA and Member States to be more open in organizing virtual pre submission meetings with applicants.

### Update of the EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders

The revision process for this Guidance document included a data call in Q4 2018. We submitted at that time substantial datasets, following extensive work – some in collaboration with Member States' authorities and responding to a clear gap identified by EFSA in its 2014 guidance version. We are disappointed to see the draft version of this revised guidance which was under public consultation recently, does not include several of these new and expected developments. We understand that time and capacity to assess these complex datasets can be a limiting factor. However, contrary to what the latest Pesticide Steering Network minutes<sup>2</sup> state, sufficient information was provided in due time to EFSA.

Please find in the annex to this letter an overview table indicating the content and status of the two main projects which are not considered in the revised version. **We would invite the Commission to mandate EFSA rapidly so as to assess these multi-year projects with an aim to incorporate the new knowledge they bring into limited revision of the guidance before its finalisation**.

We would welcome a more detailed discussion on these issues. If you have any questions regarding CropLife Europe views, please do not hesitate to contact me.

Yours sincerely



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cc. Karin Nienstedt  
Manuela Tiramani

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

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<sup>2</sup> <https://www.efsa.europa.eu/sites/default/files/2021-04/27th-meeting-efsa-pesticide-steering-network-minutes.pdf>

Annex – CropLife Europe completed project on Occupational Exposure

Project name	Project Status	Exposure scenario	Abstract	Status and further information
BROV - Worker	completed	Worker re-entry in Grapes	<p>To address a data gap, new transfer coefficient (TC) values have been proposed for vineyard workers handling treated grapevines when carrying out harvesting and maintenance activities. In this project, TCs for various activities are derived from pairs of concurrent worker exposure and dislodgeable foliar residue (DFR) studies. The Bystander Resident Orchard Vineyard (BROV) re-entry database considers five matched pairs of exposure and DFR studies carried out between 2004 and 2017. The studies were on wine grapes and cover hand harvesting, pruning, training and shoot lifting in vineyards in the Czech Republic, Germany, France and Italy. The test materials were all fungicides and the crop foliage was full at the times of application and re-entry.</p> <p>In the exposure studies, a total of 73 workers at 16 sites were monitored for a full working day. Dermal exposure of the hands and body was measured using a combination of inner and outer dosimetry clothing, hand washes and face wipes. Partial nitrile work gloves (nitrile protective coating on the fingers and palm of the hand but permeable material on the back of the hand) were also used in two studies involving 24 workers. In the DFR studies, leaf punch samples were taken at each site to correspond, as far as possible, with the time of worker re-entry.</p> <p>Potential exposure values (for both the body and the hands) showed a good correlation with the DFR values. Total (body and hands) TC values based on the BROV studies are lower than the current default values in the EFSA Guidance Document for both potential worker exposure and assuming the use of workwear with bare hands.</p>	<p>Study reports submitted to EFSA in December 2020.</p> <p>CRD project report for the re-entry part finalized.</p> <p>CRD project report for the drift part still outstanding.</p> <p>Re-entry and Drift data were notified during the EFSA open call in Q4 2018</p> <p>Original study reports were finalized already in 2017, thus could have been submitted during the data call. However, it was agreed within the BROV working group to wait for the final study evaluation report by CRD.</p>
BROV - Bystander	completed	Bystander Drift exposure, upward spraying	<p>The objective of this study set was to determine the dermal and inhalation exposure of bystanders/residents resulting from spray drift associated to Broadcast Air-Assisted Application in typical pome fruit orchards and vineyards with low or full leaf cover. In addition, potential inhalation exposure was determined from any possible volatilization for a period of seven days following the application.</p> <p>Outcome: Drift is dependent on the leaf coverage:</p> <ul style="list-style-type: none"> <li>- For low leaf cover, drift exposure is similar to the values from the current EFSA guidance.</li> <li>- For full leaf cover, drift exposure is lower than drift values from the EFSA guidance (~factor 2-3)</li> </ul>	<p>EFSA served as an Observer (with access to study reports) in this working group and no mention was made this approach would not be acceptable for EFSA for an implementation of data in the upcoming guidance revision.</p>
BREAM 2 (with add-on “drift reducing nozzles”)	completed	Bystander Drift exposure, downward spraying	<p>The current EFSA guidance for estimating bystander exposure allows maximum 50% drift reduction as a risk mitigation measure based on the use of nozzles classified as 50% drift reduction or greater. This was justifiable because drift reduction classification has been developed for exposure of aquatic species in surface water bodies and therefore relates to sedimenting spray drift. The basis of models of bystander dermal and inhalation exposure such as BREAM, BREAM2 and BROWSE (Kennedy et al, 2012, Kennedy and Butler Ellis, 2017, Butler Ellis et al, 2018) is airborne spray drift, rather than sedimenting spray drift. There has been concern expressed that the level of drift reduction measured for ground deposits might be greater than the airborne spray which is most relevant to dermal and inhalation exposure for bystanders.</p> <p>Recently, data has been obtained from the literature (Glass et al. 2002, Vermeulen et al, 2019) and from new tunnel studies that will assist in establishing whether the classified drift reduction can be used directly to adjust predicted exposures, or whether an alternative approach is required. The majority of the data considered show that the reduction in potential exposure of bystanders by using drift reducing nozzles is at least as great as the reduction in ground deposits at the same location downwind. Further analysis suggests that the potential exposure reduction is also greater than the reduction in drift as measured with either the UK, DE or NL protocols.</p> <p>It can be concluded that the drift reduction class for a given nozzle, provided that nozzle is used with the appropriate spraying conditions which include pressure and boom height, can be used to reduce the predicted exposure of residents and bystanders. This would apply to nozzles that have been classified according to the UK, NL or German protocols up to and including 90% drift reduction. A follow-up project has started to implement these findings in the BREAM 2 calculator:</p> <p><a href="https://www.ssau.co.uk/bream2-calculator">https://www.ssau.co.uk/bream2-calculator</a></p>	<p>Submitted during the open data call in Q4 2018</p> <p>No claim of data protection and availability of raw data have been confirmed by the owners (Silsoe/DEFRA)</p>