11 October 2019

Active Substance MANCOZEB:

DISCUSSION AT STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED, 21-22 OCTOBER 2019

Mancozeb Overview

- Mancozeb is one of the most used fungicides in the world, authorized in all EU Member States. Very few multisite alternatives are available in the EU (e.g. control of late and early potato blight), and Mancozeb is considered by EU farmers as crucial for resistance management.

- Mancozeb has a long history of safe use in the EU with no adverse data in the last 10 years, nor evidence of adverse effects on humans, including for its metabolite, ETU.

- Mancozeb is also pivotal to many strategic crops imported to the EU (e.g. bananas). A non-renewal would create severe trade disruption with a large number of trading partners.

- Findings of Mancozeb withdrawal cost-benefit analysis include approx. 4.8 billion EUR economic loss for EU farmers in the next 10 years and approx. 11.5 million EUR social costs.

Situation: Mancozeb is reaching SCOPAFF early in the process

- The RMS UK RAR concluded that Mancozeb does meet EU Regulation 1107/2009 renewal criteria. EFSA Conclusions however suggest some critical areas of concern and data gaps.

- Issues identified by EFSA and data gaps are largely related to a rushed evaluation process: due to the original Brexit date (29.03.19), UK had to rush the evaluation of certain data duly submitted by the Applicant (ED, birds & mammals, NTAs, soil organisms, and Toxicological Reference Values).

- In fact, due to Brexit dynamics, RMS did not consider critical information submitted by the applicant in due time, which has led to several data gaps in EFSA Scientific Opinion. This critical information did not include new data/studies; it was merely additional information or refinements based on additional information. Also, interim reports were not considered and the Applicant never received the request to submit the final versions.

- Unlike other molecules where UK was RMS, there was no transfer of the dossier to the post-Brexit RMS for a proper review of the file by a new RMS before submission to EFSA. Substances being evaluated in parallel are still being reviewed by the new RMS, leading to an unfair treatment for Mancozeb, largely reflected in EFSA Opinion.

- Moreover, despite Brexit not being yet formalized, UK has not acted as RMS since March, and is not even attending SCOPAFF meetings. In other words, there has been no RMS to defend Mancozeb for over 7 months, and the UK has been unable to advocate its initial positive conclusion.

- As the UK has exited the process, Greece will now formally act as RMS for Mancozeb.

Way forward

<u>New CLH dossier is in the pipeline to review the R1B classification</u>

- The 'R1B' classification proposed by ECHA in March 2019 RAC 48 was listed by EFSA as a "critical area of concern." There are several doubts regarding the criteria followed by RAC for such classification (most importantly, clear evidence that mancozeb was classified by association with its metabolite ETU and the proposal relied heavily on an old study with a poor Klimisch score, which has since been superseded by a number of guideline compliant studies).

- The UK, as dossier submitter, initially proposed "no R" classification, based on weight of evidence.

- A new CLH dossier is in the pipeline, including two new studies aimed at addressing specific concerns raised at RAC 47 and 48 – **this should be ready by mid-2020.**

<u>Safe use has been documented and should lead to ED assessment & potentially an Art. 4.7 derogation dossier</u>

- Safe use has been demonstrated by the notifier: one application with product in water soluble bags, wheat, outdoor and standard model refinements (operator: full PPE; resident: 5 m buffer zone).

- The safe use should lead to invitation for an "ED stop-the-clock" to address ED concerns, as done for all substances under evaluation. EFSA conclusions on ED should strictly follow the procedures foreseen under the new implementing regulation of the new ED criteria adopted in November 2018.

- With a safe use, and in the scope of the ED stop the clock, the Applicant should also be invited to submit a derogation dossier (either Negligible Exposure or Art 4.7). During its assessment, RMS UK concluded there were no reasons for submitting a derogation dossier (it concluded Mancozeb is not ED nor should be classified for developmental toxicity), and therefore an Art 4.7 or Negligible Exposure dossier could not be submitted earlier in the process.

- Despite this, the Applicant has provided a limited Art. 4.7 dossier with the original submission. However, the Commission should invite the Applicant to provide an 'updated' full dossier since new guidance on Art. 4.7 has been issued in the meantime.

October 21-22 SCoPAFF – Points to make:

Given the unique situation with Brexit and the extraordinary situations which have surrounded the evaluation process of Mancozeb, Member States are encouraged to raise the following petitions to the Commission:

- Grant sufficient time for new RMS Greece to review the file in depth and make specific comments on the EFSA Conclusion if deemed necessary, specifically reviewing critical points which were rushed or not evaluated by RMS UK during its evaluation, in order to confirm the safe use.

- Establish an ED-Stop-The-Clock to fully evaluate ED potential and if necessary, submit data to clarify any concerns under the new ED criteria, and within the same scope also invite the applicant to submit a derogation dossier.

- In case the new CLH dossier leads to re-classification of Mancozeb, mandate EFSA to review its Scientific Evaluation to update the classification comments and remove the critical area of concern (R1b).

Member States to consider the Applicant's response to the EFSA conclusion

- As part of the process, the Applicant has commented on the EFSA conclusion. The Member States are urged to not only consider the EFSA conclusion, but also the Applicant's comments when taking position on the dossier.