May 2020

Active Substance MANCOZEB: Planned Discussion at Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) 18-19 May 2020

URGENT REQUEST FROM RMS GREECE FOR MORE TIME TO EVALUATE INCOMPLETE DOSSIER;

NEW CLH SUBMISSION FROM MALTA TO REVIEW NEW STUDIES

Summary:

- The Commission has put forward a non-renewal proposal for the active substance Mancozeb for discussion under point 'C' of the Agenda at the SCoPAFF on 18-19 May. R1B classification, ED, and no safe use are stated by the Commission to justify its proposal.

- However, important developments in these three areas call for a postponement of the discussion and a review of the Commission´s proposal.

- 5.1.2.a Woo has reviewed information that was missed 5.1.2.a Woo. The preliminary evaluation concluded that there is possibly a safe use, abut a proper evaluation of this, as well as of the ED properties, should take place, and that Article 4.7 restricted approval could be envisaged. A full review of this information 5.1.2.a Woo is currently ongoing and expected to be ready in July 2020. Discussions should be placed on hold in the meantime.

- 5.1.2.a Woo evaluating institute 5.1.2.a Wo has also reviewed the dossier and concluded that a safe use is possible. 5.1.2.a Woo evaluators also conclude that procedurally, Article 4.7 could be envisaged.

- As regards the Classification with R1B, 5.1.2.a Woo have informed ECHA about its upcoming submission of a new CLH dossier for Mancozeb proposing to reclassify it as R2 in light of new scientific studies available. ECHA and the Commission have been notified in writing, and the new dossier will be ready by Q2 2020. The Registry of intentions has been updated accordingly (see attached extract)

Situation:

- 5.1.2.a Woo concluded that Mancozeb does meet EU Regulation 1107/2009 renewal criteria. The EFSA Scientific Opinion, however, suggests some critical areas of concern and data gaps.

- Issues identified by EFSA and data gaps are largely related to a 5.1.2.a Woo had to rush the evaluation of certain data duly submitted by the Applicant (ED, birds & mammals, NTA's, soil organisms, and Toxicological Reference Values), 5.1.2.a Woo.

- In fact, 5.1.2.a Woo, the RMS did not consider critical information submitted by the applicant on time, which has led to several data gaps in the EFSA Scientific Opinion. This critical information did not include new data/studies; it was merely additional information or refinements

based on available information. Also, interim reports were not considered and the Applicant never received the request to submit the final versions.

- Unlike other molecules 5.1.2.a Woo for a proper review of the file by a new RMS before submission to EFSA. Substances being evaluated in parallel where such transfer took place are still being reviewed by the new RMS, leading to unequal treatment for Mancozeb, largely reflected in the EFSA Scientific Opinion.

- 5.1.2.a Woo

- 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). This is concluded based on available information only, which was not considered 5.1.2.a Woo.

- 5.1.2.a Woo. To that effect, the deadline to review the outstanding data was given until March 2020 to allow 5.1.2.a Woo to conduct such a review. There is an excess of information currently being reviewed by 5.1.2.a Woo with essential data on endocrine disruption, Toxicological Reference Values and non-dietary exposure, the risk to birds and mammals, and the risk to non-target arthropods and soil macro-organisms yet to be taken into account to make an accurate and balanced assessment on these points. These aspects were subjected to negative findings in the EFSA Conclusion and are also reflected in the draft renewal report for Mancozeb.

- 5.1.2.a Woo has undertaken the preliminary evaluation and has confirmed that a more detailed evaluation is required, to evaluate the data which was previously not done 5.1.2.a Woo. They have requested until the end of July 2020 to finalize this evaluation.

- The assessment by 5.1.2.a Woo so far suggests a possibility for a safe use for Mancozeb:

  1) 5.1.2.a Woo is assessing the non-dietary exposure in the additional scenarios (amended GAP) considered relevant for the renewal of Mancozeb – the MTF proposed a safe use for cereals and potatoes (application reduced to one) and indoor tomatoes (the number of applications is reduced to two) – the safe use proposed by another applicant.

  2) 5.1.2.a Woo fully acknowledges that in line with Commission Regulation (EU) 2018/605, an ED assessment should be provided, considering the ECHA/EFSA ED guidance (2018). Although this was submitted in time by the applicants, this was not considered 5.1.2.a Woo states there may be a need to generate further data to conclude on the ED properties of Mancozeb in line with the Regulation.

  3) 5.1.2.a Woo provided supportive views on the additional parts of the assessment such as the risks to birds and mammals, non-target soil organisms, aquatic tox for metabolites and residues, and currently performs a more detailed evaluation.

  4) 5.1.2.a Woo believes there is no need to re-evaluate the risks to bees, non-target arthropods, and aquatic organisms.

  5) The RMS supports the new studies being conducted by the MTF in other regulatory processes which justify the new CLH dossier 5.1.2.a Woo to reclassify Mancozeb as R2, with the purpose to cover the uncertainty on the mechanism behind developmental toxicity in rats (Gallo *et al.,* 1980) given also the relevance for the risk assessment of Mancozeb (possibly no cut-off classification for Mancozeb).

- Based on the preliminary findings of 5.1.2.a Woo, the notifier reaffirms that sufficient time for the RMS should be granted to review the file in-depth and make specific comments on the EFSA Conclusion if deemed necessary, specifically reviewing critical points that were rushed or not evaluated by 5.1.2.a Woo during their evaluation, to confirm the safe use.

Conclusions of 5.1.2.a Woo Risk Evaluators:

- In addition, the 5.1.2.a Woo evaluating institute 5.1.2.a Wo has reviewed the available data and EFSA Opinion and disagrees with EFSA on several parts of the risk assessment: birds and mammals, non-target arthropods, soil organisms, phototoxicity, residues, and consumer exposure and drinking water. In other words, it concludes there is a safe use for Mancozeb.

- The safe use should lead to an 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 within 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) given the cut-off classification of R1B as concluded by RAC 48. During its assessment, 5.1.2 a Woo concluded there were no reasons for submitting a derogation dossier (it concluded Mancozeb is neither 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.

- In line with the above, the Commission should invite the Applicant to provide an Art. 4.7 dossier since new guidance on Art. 4.7 has been issued in the meantime – the dossier is ready and available for submission (a separate summary note is available, showing amongst others over 900 country/crop combinations where no alternatives to Mancozeb exist).

New CLH dossier is being launched 5.1.2. a Woo to review the Repro 1B classification

- The 'Repro 1B' classification proposed by ECHA in March 2019 RAC 48 was listed by EFSA as a "critical area of concern" and is used by the Commission as a basis for its non-approval proposal. 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, which were ignored by RAC). Notably, the UK, as dossier submitter, initially proposed a "no Reprotoxic" classification, based on weight of evidence.

- A new CLH dossier is being submitted by 5.1.2.a Woo under Article 37(6) of Regulation (EC) No 1272/2008, including two new studies aimed at addressing specific concerns raised at RAC 47 and 48, proposing to reclassify Mancozeb as Repro2. ECHA´s Registry of Intentions has been updated recently. The dossier should be formally sent to ECHA before summer.

- The potential reclassification of Mancozeb would, therefore, eliminate one of the main points leading to the Commission's non-approval proposal, the cut-off classification R1B.

Way Forward:

- In light of the above explained developments, Member States are kindly invited to consider supporting a comprehensive discussion on Mancozeb, which requires:

1) Allowing 5.1.2.a Woo to conduct a proper evaluation of crucial information duly submitted on Mancozeb yet not considered 5.1.2.a Woo. The request by 5.1.2.a Woo for July 2020 deadline should be granted to 5.1.2.a Woo to ensure proper evaluation. On that basis:

   - If safe use if concluded, the applicant should be allowed to submit a full Article 4.7 dossier (like in the case of the similar active substance Metiram, where the Applicant was invited to do so);
   - Additional ED data should be requested to the applicant;
   - EFSA should be requested to revise its Scientific Opinion to take into consideration RMS´s updated assessment;

2) Awaiting results of the new CLH dossier initiated by 5.1.2.a Woo before taking any final regulatory decision on Mancozeb, should R1B be the main reason behind the non-renewal proposal based on new RMS´s conclusions and an updated EFSA Opinion. Given that RAC 47/48 'cut-off' classification fundamentally impacted the renewal dossier yet serious scientific doubts arose about the former, the new results are critical to justify a fair and informed decision on Mancozeb.

Legal proceeding:

- MTF legal representative submitted to EU General Court an application for annulment of the EFSA decision to publish the full version of the EFSA Conclusion as well as a related application for interim relief (Cases T-620/R and T-162/20 R).

- Besides the confidentiality aspects, one of the key arguments was based on the fact that the conclusion of the full version of the EFSA Conclusion will be premature since (i) 5.1.2.a Woo is currently reviewing the data which have not been assessed 5.1.2.a Woo and (ii) this assessment is likely to change the EFSA Conclusion.

- By Order dated 7 April 2020, the president of the General Court has suspended the publication of EFSA's Conclusions until the interim proceedings are fully resolved. In the meantime, the EFSA Conclusion, whose validity is currently being reviewed by the General Court, should not be considered as a basis for deciding on the non-renewal of the substance Mancozeb.

Mancozeb Background:

- 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.