1 OPGAVEBESKRIVELSE/ ASSIGNMENT DESCRIPTION

1.1 Baggrund for opgaven/ Background

As Rapporteur Member State (RMS) Denmark is obligated to perform a hazard identification for endocrine-disrupting properties of tebuconazole by following the scientific criteria which are outlined in Commission Delegated Regulation (EU) 2017/2100 and Commission Regulation (EU) 2018/605 for biocidal products and plant protection products, respectively. The assessment should be performed in line with the EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

1.2 Opgavens indhold/ Contents of the assignment

- A draft report of the endocrine disrupting properties (ED) of tebuconazole consisting of Appendix I (EFSA administrative GD 2019) and supported by an Appendix E1 has been provided by applicant. This draft ED assessment report from applicant should be critically evaluated, revised and assessed according to "Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009"[1] by the consultant. The final report of the endocrine disruptions properties of tebuconazole should represent the view of the Rapporteur Member States/RMS (DK authorities).
  Follow up question during the EU commenting period on the ED assessment report and possibly participation in the expert meeting of the consultant are expected.

- In addition to the ED assessment the consultant should provide a re-evaluation of the proposed classification for reproductive toxicity according to the CLP criteria based upon the studies summaries and other information provided in the revised monograph, Volume 3. B.6.6, Volume 1 and the information provided in the draft ED assessment report.

Note bene: The assignment for the consultant is only related to assessing the endocrine disrupting (ED) properties for human health; environment is not part of this project.

[1] EFSA/ECHA ED GD 2018 https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5311

1.3 Krav til opgavens udførelse/ Terms of reference (ToR)

In the dRAR Vol 3 the specific studies are presented and evaluated by the RMS (UK, now DK). It is expected that the consultant undertakes a representative sampling of the information in Appendix E to check the key studies with ED related endpoints and that the results are presented correct including the systemic toxicity endpoints of these studies. It is essential that the Appendix E is trustworthy as the lines of evidence are based on this information. If data are missing or not correct in Appendix E this should be added/corrected in a new version of Appendix E.

If the consultant need to go through specific studies (study reports), a list should be submitted to DEPA and the studies will be provided. If, in this work, the consultant come across important results that are not presented in the study summaries and the evaluation from the RMS in Vol 3 B.6 this should be commented and a proposal for addition to the text added.

The literature search done by the applicant in the draft ED assessment report should be check for compliance with the guidance given for systematic literature search in EFSA/ECHA ED GD 2018. If the consultant come across data from open literature that is not represented, validated and assessed or the relevance assessment of the included studies is different than the consultants view this should be commented and if possible added to Vol 3 B6 and appendix E.

Follow up question during the commenting period on the ED assessment report and participating in the expert meeting of the consultant are expected

Deliveries for ED:

1) Overview or explanation of the thorough sampling of Appendix E
2) Update Appendix E if found necessary going through the database.
3) New Appendix I – based on applicants drafts of Appendix I, updated Appendix E, study summaries and assessment of studies in vol 3 B.6 and if necessary relevant study reports
4) Updated vol 3 B.6 with relevant comments and track changes where necessary.
5) Testing strategy in vol 1 if studies are missing to clarify ED potential
6) Follow up question during the EU commenting period on the ED assessment report and participating in the expert meeting of the consultant are to be expected.

The consultant are requested to provide their proposal and justification for classification directly in Volume 3. B.6.6 and Volume 1 section 2.6.6 summary of reproductive toxicity.

Deliveries for CLP classification:

1) Updated vol 3 B.6.6 if necessary based on a thorough examination of the database on reproductive toxicity.
2) Updated vol 1 section 2.6.6

All changes made by the consultants to the different documents should be provided with track-changes and additional question, justification or comments to DK EPA could be inserted as commentary notes.

Additional guidance on ED assessment can be found in the following links:

EFSA/ECHA ED GD 2018:

https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5311

(under supporting information contains Appendix E1 and E2)

EFSA Admin GD 2019:
https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1612

(under supporting information; a zip fil with a wordversion of appendix I exists)

1.4 Formål og succeskriterier/ Objectives and success criteria

An assessment of the endocrine disrupting properties of the active substance tebuconazole in line with the EFSA/ECHA ED GD (2018) shall be conducted by the consultant, on behalf of RMS DK. The purpose is to assess whether the information available in the application dossier is sufficient to conclude on ED properties or not and if not to propose a testing strategy. Another purpose is to conclude whether the approval criteria on endocrine disrupting properties are met.

An assessment of the reproductive toxicity of tebuconazole and comparison with the CLP criteria for the purpose of a classification/non-classification proposal.

Success criteria

The deadlines for the consultant are meet; otherwise, EU deadlines will not be meet.

The scientific quality of the draft/final report from the consultant is of high standard resulting in minimal revision work for MST.

1.5 Bemanding/Required qualifications

Minimum qualifications for professional competences:

- A senior toxicologist with in depth scientific experience and insight in EFSA procedure and practice should be involved in the ED assessment of tebuconazole and validate all crucial conclusions in Appendix I (e.g WoE & designated scenarios, MoA analysis etc.) and ensure the ED assessment is done in line with the guidance given in EFSA/ECHA ED GD 2018.
- Experience with toxicological risk assessments of pesticide and biocide active substances.
- Experience with classification of chemicals according to the CLP Regulation 1272/2008.
- Sufficient personnel with adequate competences in order to ensure quality control of the delivery.

Tidsplan

Start for consultant: 16/6-2020

Draft ED report and a re-evaluation of the proposed classification for reproductive toxicity according to the CLP criteria from consultant to MST: **7/8 -2020** (MST revision time four weeks due to vacation)

MST revision of draft ED report and a re-evaluation of the proposed classification for reproductive toxicity according to the CLP criteria to consultant**: 4/9-2020**

Final ED report and a re-evaluation of the proposed classification for reproductive toxicity according to the CLP criteria from consultant to MST: **11/9-2020**

1.6 TIMETABLE

The advertisement is expected to be completed according to the timetable below. It should be noted that the contracting authority reserves the right to make changes. Bidders will be notified of such changes.

Wednesday 20. May 2020	Advertisement on www.udbud.dk
Tuesday 2 June 2020 at 12.00	**Deadline for asking questions**
Tuesday 9. June 2020 at. 12.00	**Deadline for submission of offers**
Friday 12. June 2020	Expected provision of notifications regarding the award decision to bidders
Tuesday d. 16 June 2020	Contract signing and eventual kick-off meeting