Appendix 1 – Specification of requirements

Specification of requirements for project on revising the Northern zone higher tier Birds and Mammals risk assessment guidance document.

Background

In 2012-13 the Scandinavian and Baltic countries developed a higher tier risk assessment guidance document (NZ B&M GD) to be used for pesticide risk assessment for birds and mammals in the Northern zone. The NZ B&M GD shall be used in relation to approval of pesticide products if the risk to birds or mammals is not addressed following the EFSA Birds and Mammals guidance document. i.e. the NZ B&M GD give guidance on crop and growth stage specific focal species for higher tier risk assessment, and specify both the related input parameters and the accepted refinement options.

This NZ B&M GD is based on literature data, information from applicant and expert knowledge on behaviour of birds and mammals. New data have become available since the guidance document was published and experience from use of the guidance document over the last 5 years both by applicants and risk assessors has created a need for updating the document. e.g. development of additional scenarios and guidance on further refinement options, especially for seed treatment.

This revision of the NZ B&M GD will be initiated as the revision work on the EFSA B&M GD, but much shorter time, than the EFSA revision is foreseen. The revision of the NZ B&M GD is initiated now, as additional scenarios and refinement options are needed before the EFSA B&M GD revision is finalised.

Findings for the revision of the NZ B&M GD may have bearings on the EFSA revision work and visa-versa.

Revision needs

The existing NZ B&M GD is the basis for updating and the existing concepts and scenarios should not be changed unless they are deemed as a part of the revision i.e. if there are new data in the area, it's a new scenario or if refinement options should be amended (e.g. seed treatment).

Specific requirements for revision

The following issues should be part of the revision:

- Search, assessment and possible inclusion of new knowledge e.g. on PD and PT data. The assessment and possible proposal for revising the GD shall follow the approach already taken in the GD. Consultant is expected to be involved in
 - generating search terms (DK assistance is expected to carry out actual search and screen results)
 - assess relevant data from search and consider if and how that is incorporated in GD.
 - assess possible industry data
- Develop more guidance on how to acquire and use residue data/degradation data. What is required (data, degradation kinetics) and how is it used.
- Development of a new scenario for Christmas trees: Relevant bbch/season distribution of scenario and relevant FS (birds/mammals), diet (PD) and behavior (PT).
- Develop better refinements options in seed treatment risk assessment
- Update spreadsheet

Expertise required

An expert should ideally have knowledge on:

- Birds and/or mammals
- Birds and mammals pesticide risk assessment
- Bird and/or mammal surveillance
- Agricultural practice

Budget

We expect a budget around 25000 euro.

Staffing/management

• A NZ revision task force (RTF) of 4-5 persons is established with representative ecotoxicology pesticide risk assessors from competent authorities in the Northern zone:

Signe Pedersen, P&G, Danish EPA Sandra B. Lassen, P&G, Danish EPA Audun Storset, Mattilsyn, Norway NN, Kemi, Sweeden Alf Aagaard, P&G, Danish EPA (chair)

- The role of the taskforce is to guide on scientific issues, help in ensuring timelines and comment on draft revision, by e-mail correspondence and telephone conferences (3-4)
- A consultant to assess and draft revised version of NZ B&M GD, who will participate in the taskforce
- The consultant is responsible for implementing decisions from the taskforce
- Support for literature search/screening
- DEPA (Alf Aagaard) will manage the project

Timeline

Date	Issue	Comments
December 2018	Call for procurement	
January 2019	A contract including timelines is agreed	
Start February 2019	TC including RTF research assistant and consultant	
Start March	TC including RTF, consultant and applicants	
March - April	Data collection, assessment and draft revised NZ B&M GD	
Start May	TC between RTF and consultant	
Midt May	Consultant submit draft revised Guidance document	
Late May	Commenting phase NZ MS	
Start June	Consultant update revised draft	
End June	RTF approve revised draft for NZ for NZ ecotox TC	

Data sources

Open literature search (Consultant/RTF provide search terms and DEPA run search/screening)

Industry data (discuss with ECPA)
NZ MS data (e.g. NO publ. on bird sp)
EFSA conclusions/general ecotox meeting minutes (e.g. how to deal with residue data)