April, 2014

**Guidance Note on Higher Tier Birds & Mammals Risk Assessment in Denmark**

**Background and purpose**

This Guidance Note describes a number of options for refinement of the risk assessment for birds and mammals, which apply to national registrations of plant protection products in Denmark.

The Guidance Note shall be viewed in the context of the following documents:

* Guidance Document on Work-sharing in the Northern Zone in the Authorization of Plant Protection Products, April 2013

<http://www.mst.dk/NR/rdonlyres/F8172436-A8B5-4205-BCA6-029ABAF8B958/0/NorthernZoneworksharingguidance_April2013.pdf>

* Framework for the Assessment of Plant Protection Products. Danish Environmental Protection Agency, February 2013

<http://www.mst.dk/NR/rdonlyres/A9A1B9EE-084E-46AA-BAE4-F0B573D4FDCC/0/DKFrameworkpesticideRAjan2013final.doc>

* Guidance of EFSA: Risk Assessment for Birds and Mammals. EFSA Journal 2009; 7(12): 1438

<http://www.efsa.europa.eu/en/efsajournal/doc/1438.pdf>

* Pesticide Risk Assessment for Birds and Mammals. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009, January 2014 (version 1.1)
<http://mst.dk/media/mst/9038564/Birds-and-mammals-higher-tier-risk-assesment-Northern-Zone2014April-ver1-1.docx>

and the accompanying Calculation Tool (version 1.1)

<http://mst.dk/media/mst/9038561/Bird-mammal-scenario-template_v1-1.xlsm>

Tier 1 risk assessment for birds and mammals within the Northern Zone is performed in accordance with Guidance of EFSA (2009) with a few amendments as described in section 4.6.3 of the Guidance Document on Work-sharing in the Northern Zone.

Higher tier risk assessment is performed according to the Northern Zone Guidance Document “Pesticide Risk Assessment for Birds and Mammals”. The list of refinement options provided in this Guidance Document is considered as exhaustive, i.e. no further refinements are generally accepted for the Core assessment.

In Denmark, however, some further refinements of the risk assessment may be applicable. The aim of this Guidance Note is to provide an overview and a short description of these refinement options. Higher tier risk assessments making use of these options shall be presented in the Danish national addendum.

The Guidance Note is intended to serve as guidance to applicants and shall also facilitate a standardised assessment by the Danish Environmental Protection Agency.

All refinement options described in the following tables may be implemented using the Northern Zone Calculation Tool.

**Summary of Danish mandatory deviations from the Core assessment**

|  |  |  |
| --- | --- | --- |
|  | **Northern Zone Core assessment** | **Denmark** |
| Endpoints | Acute LD50 (birds and mammals): Geometric mean approach is accepted, cf. EFSA (2009) section 2.4.1 | Acute LD50 (birds and mammals): Geometric mean approach is not accepted; worst case LD50 is used\* |
|  | Reproductive endpoint (birds):Geometric mean LD50/10 is used if lower than NOAEL | Reproductive endpoint (birds):Geometric mean LD50/10 is used if lower than NOAEL (i.e. no deviation from Core assessment) |

\* Cf. Footnote 9 in the Guidance Document on work-sharing

**Summary of Danish refinement options**

(NZ GD = Northern Zone Guidance Document “Pesticide Risk Assessment for Birds and Mammals”)

|  |  |  |
| --- | --- | --- |
|  | **Northern Zone Core assessment** | **Denmark** |
| Pelleted beet seeds | Follows EFSA GD for birds and mammals risk assessment (only relevant for birds as mammals eating pelleted beet seeds (wood mouse) crack and discard the pellet with most of the residue before ingesting the seed | Sowing of pelleted sugar beet and fodder beet seeds is carried out with special sowing equipment that sows the seed in the soil with a band. In this way seeds are sown precisely at a specific depth and at a specific distance from one another. The Danish Environmental Protection Agency finds that there is no exposure to wild birds and mammals for this use |
| Focal species | Whinchat *Saxicola rubetra*:Focal species in cereals (BBCH 40-89 and pre-harvest desiccation)Willow warbler *Phylloscopus trochilus*:Focal species in maize (BBCH 30-39) | Whinchat and Willow warbler are not considered relevant focal species in agricultural fields 1For all other focal species, the Summary Tables in chapter 6 of the NZ GD apply |
| Proportion of diet (PD) | Acute risk:No refinement of the Tier 1 diets (EFSA 2009 appendix A) is accepted | Acute risk:The crop and growth stage specific PD values in the NZ GD can be used; see chapter 5 (sections “Risk assessment”) and appendices 3 & 4 in the GDTER values must be calculated for all relevant combinations of growth stage and month; worst case TER is used |
|  | Long-term (reproductive) risk:The crop and growth stage specific PD values in the NZ GD can be used; see chapter 5 (sections “Risk assessment) and appendices 3 & 4 in the GD | Long-term (reproductive) risk:The crop and growth stage specific PD values in the NZ GD can be used (as in the Core assessment)TER values must be calculated for all relevant combinations of growth stage and month; mean RUD is used for each focal species |
| Residues(RUD) | Standard RUD values (EFSA 2009 appendix F and NZ GD Table 4.1) may be supple­men­ted (*not* replaced) by residues from relevant studies. The recommendations in EFSA 2009, section 6.1.4, are followed (cf. section 4.3 of the NZ GD) | The assessment follows the same principles as described for the Core assessment. New additional data will be evaluated on a case-by-case basis and *may* replace the standard values if they are considered more representative 2The evaluation of the representative­ness of new data is based on:* Number of sites
* Relevance of sites in relation to Danish conditions

Any decision on replacement of the standard RUDs will also depend on the amount of data on which the standard RUD values are based 3 |
| Residue decline(DT50) | Refinement of the standard DT50 (10 days) is accepted if based on data from at least 4 sites, which are considered relevant for Northern Zone conditions 4* 4 to 10 sites: worst case DT50 is used
* > 10 sites: arithmetic mean DT50 is used
 | Refinement of the standard DT50 (10 days) is accepted if based on data from at least 2 sites, which are considered relevant for Danish conditions and for the crop in question* 2 or 3 sites: worst case DT50 is used
* ≥ 4 sites: arithmetic mean DT50 is used
 |
| Interception | Tiered approach:Step 1: Interception factors in Table 4.2 of the NZ GD are used; no interception is considered at earlier growth stagesStep 2: Interception factors in Tables 4.3 and 4.4 of the NZ GD are used 5; however country-specific restrictions to the use of these values apply for Norway, Sweden, Finland and Latvia (see NZ GD section 4.5) | Use of the following values is accepted:* Interception factors in Tables 4.3 and 4.4 of the NZ GD 5 *or*
* Deposition factors tabulated in Annex 14 of the Danish EPA’s Framework for the Assessment of Plant Protect­ion Products (February 2013); upper limit of the 80 percent confidence interval is used if available 5
 |
| Proportion of Time (PT) | Acute risk:No refinement of PT is accepted; PT = 1 | Acute risk:PT may be refined if estimates for the species and crop scenario in question are available (from NZ GD chapter 5 or from case-specific studies). Some read-across between structurally similar crops is acceptable but must be duly justified in each caseThe 90th percentile of the PT distribution for “consumers” is used |
|  | Long-term (reproductive) risk:PT may be refined if estimates for the species and crop scenario in question are available (from NZ GD chapter 5 or from case-specific studies). Some read-across between structurally similar crops is acceptable but must be duly justified in each caseThe 90th percentile of the PT distribution for “consumers” is used 6 | Long-term (reproductive) risk:PT may be refined if estimates for the species and crop scenario in question are available (as described for the Core assessment)Mean PT for “consumers” is used |

1 Willow warbler would still be relevant for use in energy crops (f.x. energy crops like willow or poplar).

2 Even if EFSA peer review expert meetings have confirmed new RUD values, their validity under Danish conditions has to be assessed.

3 Standard RUDs for plant shoots and leaves, and to some extent also for foliar and ground-dwelling arthropods, are considered more reliable than the standard RUDs for other food items.

4 In cases a lower number of data, which indicate a very rapid decline, are available, other relevant information may be used a supporting data (e.g. data on hydrolysis or volatilisation).

5 It shall be borne in mind that these interception/deposition factors are intended to describe the amount of pesticide that reaches the soil surface and that the deposition on weeds and ground-dwelling arthropods may in some cases be higher. For instance, although an interception factor of 90 % is stated as applicable for spraying on established turf, deposition on ground-dwelling arthropods will most probably be higher than 10 % of the applied dose.

6 The 90th percentile for “all birds/mammals” may be used if all of the tracked individuals were caught within (or in close proximity to) the target crop, cf. EFSA (2009) section 6.1.5.2.