

## EFSA B&M Guidance Document – errors and points of clarifications

Whilst using the EFSA Guidance Document of Risk Assessment for Birds and Mammals (EFSA-Q-2009-00223) several errors in the text have been noticed. These have been collected in this document which will be updated if additional errors are found. In addition clarification is helpful in some areas, so these have also been included.

### 1. Risk from spray applications:

- a. Section 4.1 – *Avian screening step* (Table 6): The acute shortcut value for bare soils and hops should be **25.3** (not 24.7). Bush and cane fruit should be **52.2** (not 46.3). The correct values are given for the reproductive assessment.
- b. Section 4.1 – *Tier 1 selection of B&M focal species*: Include all focal species relevant to timing of application.
- c. In Appendix A1 (table line 82) the FIR/bw for wood pigeon in leafy vegetables BBCH 10-19 does not fit the diet description. The FIR/bw *should be 0.79, which gives a mean shortcut of 26.7* and a 90<sup>th</sup> percentile shortcut of 55.5. These corrected values should also be used in Annex I, Table I.1, Leafy Vegetables BBCH 10-19, medium herbivorous/granivorous bird “pigeon”.
- d. Section 4.4 – In Step 9 reference is made to the multi generation study/studies but in the further information (p42 under the heading “Examination of additional mammalian toxicity studies”) other mammalian toxicology studies are referenced, so all the relevant mamtox data should be considered.

### 2. Risk from Granules:

- a. *Ingestion of granules as grit* (birds only): *In Section 5.1.2 (p44) the DGritDacute formulae give an endpoint for either a large bird or a small bird. According the EPPO risk assessment (see EPPO 2003), a small bird is 25 g and a large bird is 300 g. It is important that the DGritDacute figures are corrected to bird size (or normalised to kg bw) before calculating TERs (the acute TER could be underestimated by a factor of 40 without this correction).*
- b. *Other grit scenarios*: All other granular risk assessment calculations are based on kg bw, therefore no further correction/normalisation is required.

### 3. Risk from seed treatments:

- a. Section 5.2.1 - *Selection of scenarios*:
  - i. Steps 1 & 2 are used to assess the risk from consumption of the treated seed.
  - ii. Step 3 is used to consider the risk from consumption of contaminated seedlings. Therefore, Step 3 is only required if the compound is systemic.
- b. *Use of terminology is misleading*: E.g. at Step 3, Table 19, ‘shortcut values’ are effectively DDDs (effects concentrations x

FIR/bw). Shortcut values in the spray application assessment are the RUD x FIR/bw and need to be multiplied by the application rate to calculate the DDD.

- c. *Missing generic focal species in Step 3*: As relevant indicator species for the risk assessment for treated seeds (crop seedlings), large herbivorous birds and mammals and small omnivorous birds and mammals are requested in the text. The generic focal species and the appropriate shortcut values for the risk assessment for pesticides present in newly emerged crop shoots can be selected from Table 19. However in the table large herbivorous birds are missing. The DDD for the large herbivorous birds (goose) should be  $0.3 \times \text{NAR}/5$  and for large herbivorous mammals (rabbit) should be  $0.4 \times \text{NAR}/5$ .
- d. Section 5.2.2 – *Step 4 TER calculations*: The long-term TER calculation is a little ambiguous: **NOAEL/ “appropriate exposure estimate”**. There is no generic default DT50 for residues on seeds, therefore in the absence of data, the exposure is the nominal application rate (NAR) x FIR/bw. If residue dissipation/ degradation data are available, then a ftwa can be calculated (with a suitable averaging time) to estimate a more realistic exposure, i.e.  $\text{NAR} \times (\text{FIR}/\text{bw}) \times \text{ftwa}$ . The UK considers that it may be appropriate to use the default value of 0.53 used for foliage degradation.

4. Refinements:

*Appendix H – use of refined  $\text{MAF}_m$  and twa values*: for multiple applications, a ‘moving time window’ approach should be used to ensure the exposure is not underestimated. The calculations illustrated in this section are incomplete.

5. Appendix 1:

- a. The column heading “Interception” is wrong – the values shown are “Deposition”.