Tables for a risk envelope check for ecotoxicology

Step 1: Identification of relevant guidances

First step of performing a risk envelope approach is determining which are the relevant guidances (see SANCO /11244/2011 rev 5 section 7.5, p 16: ' As the methods and models for the calculation of the exposure are specified in the relevant guidance documents, generally, the relevant guidance documents have to be applied in order to identify the critical GAP.').

According to the Regulation 1107, all requests for authorization should be assessed in the light of current scientific and technical knowledge (article 29 .1(e), 36). This means that generally for the new proposal, the risk assessment should be up to date according to the guidance applicable for the request for authorization.

Data requirements PPP *(new EC 284/2013 or old EC 545/2011)*			New EC 284/3013		
Aspect	EU Guidance original authorization	EU Guidance current submission	Do new data requirements apply?	**Remarks**	conclusion
Birds		EFSA Journal 2009; 7(12): 1438)			
Mammals		EFSA Journal 2009; 7(12): 1438)			
Aquatic organisms		Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015)			
Bees		Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002			
Non-target arthropods		ESCORT 2 (Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002)			
Earthworms		Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002			

Soil arthropods		Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002			
Soil micro organisms		Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002			
Non-target plants		Guidance Document on Terrestrial Ecotoxicology: SANCO/10329/2002			

Conclusion step 1:

Step 2: Identification of the critical GAP

For each aspect of the risk assessment, the critical gap should be considered by checking certain key parameters. The key parameters are described in SANCO /11244/2011 rev 5 (see chapter 7.5.). It should be noted that as this guidance was noted in 2011, the key parameters from updated scientific guidance documents for ecotoxicological risk assessment are not included. Therefore for these new scientific guidances additional key parameters might be relevant. Therefore these additional key parameters have been considered in the table as well, and can be added if they become relevant.
The guidance also notes that in case of higher tier assessment, the critical GAP might shift (7.5, p 16):' *It further should be considered that in case that the relevant trigger values according to Annex VI are breached by the worst-case GAP a refined risk assessment is required which might take into account more realistic assumptions as specified in the respective guidance documents or mitigation measures should be proposed. As such refinement steps often are very specific for a crop, region, application timing, etc. it should be carefully considered whether these assessments still cover the lower risk GAPs. If this is not the case the identification of the critical GAP should be started again excluding the GAP addressed by the refined assessment.*
This means that in cases that a higher tier refinement is required, the risk envelope approach is not very clear at it should carefully be considered which refinement parameters can be extrapolated.
The section numbers below refer to the section numbers described in SANCO/11244/2011 rev 5.

7.5.1 Birds and mammals

The SANCO /11244/2011 rev 5 has included key parameters from the birds and mammals guidance documents, the SANCO/4145/2000, final 2002and the EFSA 2009 guidance:

7.5.1.1 SANCO/4145/2000, final 2002

Birds

crop	Application rate	Interception values[1]	Number of applications/ application interval; or MAF	Crop group[2]	Higher tier refinement?	remarks
Authorized uses						

Intended uses						
Conclusion						

[1]As indicated in the guidance or in the refined assessment
[2]grassland, cereals early, cereals late, orchards/vine/hops. Seed treatments should always be treated separately

Mammals

crop	Application rate	Interception values[1]	Number of applications/ application interval; or MAF	Crop group[2]	Higher tier refinement?	remarks
Authorized uses (in case of extended uses, label changes)						
Intended uses						
Conclusion						

[1]As indicated in the guidance or in the refined assessment
[2]grassland, cereals early, cereals late, orchards/vine/hops. Seed treatments should always be treated separately

Drinking water, secondary poisoning: see exposure to surface water (fate) and exposure to soil (fate); log Pow
Conclusion:

7.5.1.2EFSA 2009

Birds

crop	Crop group[1]	Dose rate	Number of applications/ application interval; or $MAF_{50/90}$	Indicator species/ Focal species[2]	Short-cut value (acute/chronic)[3]	Effective rate	Higher tier refinement?	In risk envelope?
Authorized uses								
Intended uses								

Conclusion								

[1]As indicated in the guidance p 27, table 5
[2]In case that no higher tier refinements are used, it is accepted to only discuss the worst-case.
[3]See annex 1, depending on BBCH

Mammals

crop	Crop group [1]	Dose rate	Number of applications/ application interval; or $MAF_{50/90}$	Indicator species/ Focal species[2]	Short-cut value (acute/chronic)[3]	Effective rate	Higher tier refinement?	In risk envelope?
Authorized uses (in case of extended uses, label changes)								
Intended uses								
Conclusion								

[1]As indicated in the guidance p 27, table 5
[2]In case that no higher tier refinements are used, it is accepted to only discuss the worst-case.
[3]See annex 1, depending on BBCH

Drinking water: based on worst-case application rate and concentration of spray solution
Secondary poisoning: see exposure to surface water (fate) and exposure to soil (fate)
Conclusion:

7.5.2 Aquatic organisms

The critical GAP is mainly driven by PEC sw from the fate section. Note that for the cases where mitigation measures are prescribed on the label of original authorization, for the new requests for authorization of minor use it should be checked as well if those measures can be applied.
With the update of the new aquatic guidance (EFSA 2013) the applicability of an ETO-RAC and ERO-RAC; or refined exposure tests/pulse exposure tests should also be checked.

Aquatic organisms

crop	Fate conclusion	Mitigation measures required?	Higher tier refinement: depending on number of applications/ application interval/ application season[1]	remarks

Authorized uses				
Intended uses				
Conclusion				

[1] the applicability of an ERO- RAC or ETO-RAC for a specific use, as well as the applicability of a refined exposure tests depend on number of applications/ application interval/ application season and whether an MDD analysis is present for the mesocosm study in the original evaluation. Refinements such as geomean, HC_5 are not depending to such factor and can be extrapolated.

7.5.3 Bees

Based on the old terrestrial guidance (SANCO/10329/2002), the main relevant key factors is single application rate. However the guidance on risk envelope SANCO /11244/2011 rev 5 also mentions growth stage, application method. Additional parameters should be checked in case of a systemic mode of action (flowering, honeydew), or seed treatment (coating types relevant for dust drift)

Bees

Crop	Application rate	Application method[1]	Growth stage? Flowering? Attractive to bees?	Systemic exposure	Mitigation measures	Higher tier refinement?	Remarks
Authorized uses							
Intended uses							
Conclusion							

[1]foliar spray, application to the soil, into soil applications, greenhouse vs field applications, seed treatments etc.

The new data requirements and the coming new bee guidance might add additional key parameters

7.5.4 Non-target arthropods

Relevant key parameters in the lower tiers are application method, growth stage, application rate, number of applications, interval between applications (MAF) and drift. Extrapolation of higher tier refinements such as field studies should be checked.

Non-target arthropods

Crop	Application rate	Application method[1]	Growth stage (foliage dwelling, soil dwelling, in-soil)	MAF	Drift	Mitigation measures	Higher tier refinement?	Remarks
Authorized uses								

Intended uses								
Conclusion								

[1]foliar spray, application to the soil, into soil applications, greenhouse vs field applications, seed treatments etc.

7.5.5 Soil organisms

The critical GAP is mainly driven by PEC soil from the fate section. Extrapolation of higher tier refinements such as field studies should be checked.

Soil organisms

crop	Fate conclusion	Higher tier refinement?	remarks
Authorized uses			
Intended uses			
Conclusion			

7.5.6 Non-target plants

According to the guidance on risk envelope the key parameters are the same as for non-target arthropods. Relevant key parameters in the lower tiers are application method, growth stage, application rate, number of applications, interval between applications (MAF) and drift. Extrapolation of higher tier refinements such as field studies should be checked.

Non-target plants

Crop	Application rate	MAF	Drift	Mitigation measures	Higher tier refinement?	Remarks
Authorized uses (in case of extended uses, label changes)						
Intended uses						
Conclusion						