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Commission Notice of XXX

Step wise implementation of the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

Comment [HS1]: To be moved to title page.

On 27 June 2013, the European Food Safety Authority adopted a Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees)¹ and re-published on 4 July 2014 (*hereinafter*, the '*EFSA Guidance Document*'). This document provides Member States (MS) and applicants with guidance on how to assess the risks to honey bees, bumble bees and solitary bees from exposure to pesticides.

In December 2013, a workshop of risk managers and risk assessors from MS concluded that the EFSA Guidance Document could not be used fully and immediately, because not all the scientific methodology was yet ready to be applicable in each area of the risk assessment. A step-wise implementation of the EFSA Guidance Document was proposed.

After further consultation with the Standing Committee on Plants, Animals, Food and Feed and aiming at a harmonised and efficient implementation, the Commission notifies that the published EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees) is to be implemented as follows:

- 1) The chapters of the EFSA Guidance Document listed in Part A should be used for the assessment of applications for the approval or renewal of approval of active substances and for the assessment of applications for an authorisation or a renewal of authorisation of plant protection products for which a dossier is submitted after 30 June 2019 .
- 2) The chapters of the EFSA Guidance Document listed in Part B should be used for the assessment of applications for the approval or renewal of approval of active substances and for the assessment of applications for an authorisation or a renewal of authorisation of plant protection products for which a dossier is submitted according to the different deadlines included in the table.
- 3) Part C lists further actions proposed in order to allow for full implementation of the EFSA Guidance Document.

¹ European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295 Available online: www.efsa.europa.eu/efsajournal.

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Part A

Parts of the EFSA guidance document to be used for applications submitted after 30 June 2019

HONEYBEES

<i>Screening step spray applications</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
Acute contact adults	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD Test Guideline 214	Chapter 3.2.1 Table 2
Acute oral adults	ETR > 0.2	OECD Test Guideline 213	Chapter 3.2.2 Table 3
Chronic adults	ETR > 0.03	OECD Test Guideline 245	Chapter 3.2.2 Table 3
Larvae	ETR > 0.2	OECD Guidance Document 239	Chapter 3.2.2 Table 3
Exposure from surface water	ETR _{acute} adults > 0.2; ETR _{chronic} adults > 0.03 ETR _{chronic} larvae > 0.2	Use highest PEC _{sw} from FOCUS step 1 or RAC for aquatic organisms.	Chapter 3.5.2
Exposure from puddle water	ETR _{acute} adults > 0.2; ETR _{chronic} adults > 0.03 ETR _{chronic} larvae > 0.2	Use run-off PEC values from FOCUS	Chapter 3.5.3
Exposure to plant metabolites			Chapter 3.6
<i>Screening step solid formulations</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>

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Acute contact adults	HQ >14	OECD Test Guideline 214	Chapter 3.3.1 <i>f_{dep}</i> from Table H1b
Acute oral adults	ETR > 0.2	OECD Test Guideline 213	Chapter 3.3.2 Table 7
Chronic adults	ETR > 0.03	OECD Test Guideline 245	Chapter 3.3.2 Table 7
Larvae	ETR > 0.2	OECD Guidance Document 239	Chapter 3.3.2 Table 7
Exposure from surface water	ETR _{acute} adults > 0.2; ETR _{chronic} adults > 0.03 ETR _{chronic} larvae > 0.2	Use highest PEC _{sw} from FOCUS step 1 or RAC for aquatic organisms.	Chapter 3.5.2
Exposure from puddle water	ETR _{acute} adults > 0.2; ETR _{chronic} adults > 0.03 ETR _{chronic} larvae > 0.2	Use run-off PEC values from FOCUS	Chapter 3.5.3
<u>Exposure to plant metabolites</u>			<u>Chapter 3.6</u>
<i>Refined risk assessment for exposure via nectar and pollen following spray applications</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
Refined exposure estimates ETR _{acute} ; ETR _{chronic} ; ETR _{larvae} for all relevant scenarios	ETR _{acute} > 0.2 ETR _{chronic} > 0.03 ETR _{larvae} > 0.2	OECD Test Guideline 213 OECD Test Guideline 245 OECD Guidance Document 239	Chapter 3.2.2 Ef-values from tables X1a and X2a as appropriate for the relevant scenario SV-values from Tables Jx and Jy as appropriate for the

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			relevant scenario
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		Based on EPPO 2010 and OECD 2007 with further details as provided in Appendix O	Chapter 6.1.2 and Appendix O
<i>Refined risk assessment for contact exposure following spray application</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
Refined exposure estimate	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD Test Guideline 214	f_{dep} values from Table H1a and further guidance in Appendix H
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007 with further details as provided in Appendix O especially regarding the use of statistics and the number of colonies and fields needed.	Chapter 6.1.2 and Appendix O
<i>Refined risk assessment for exposure via nectar and pollen</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA Guidance Document of</i>

<i>following seed treatment or granule application applications</i>			<i>4 July 2014</i>
Refined exposure estimates ETR _{acute} ; ETR_{chronic} ETR; ETR_{larvae} for all relevant scenarios	ETR _{acute} > 0.2 ETR _{chronic} > 0.03 ETR _{larvae} > 0.2	OECD Test Guideline 213 OECD Test Guideline 245 OECD Guidance Document 239	Chapter 3.3.2 SV-values from Tables Jxx and Jyy as appropriate for the relevant scenario Ef values from Table X1c
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007 with further details as provided in Appendix O especially regarding the use of statistics and the number of colonies and fields needed.	Chapter 6.1.2 and Appendix O
<i>Refined risk assessment for contact exposure following seed treatment or granule application</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
Refined exposure estimate	HQ >14	OECD Test Guideline 214	Chapter 3.3.2 Ef-values from Table X1b SV-values

			from Table Jxx
Consider risk mitigation measures			Chapter 9 Appendix S
Consider further refinement of exposure estimate			
Semi-field and field effects studies		EPPO 2010 and OECD 2007 with further details as provided in Appendix O especially regarding the use of statistics and the number of colonies and fields needed.	Chapter 6.1.2 and Appendix O
Exposure to plant metabolites			Chapter 3.6

Part B

Parts of the EFSA guidance document to be used for applications submitted after 30th June 2021 publication of the revised EFSA Guidance Document on the risk assessment for bees

HONEYBEES

	<i>Guideline/test protocol</i>	<i>Implementation date</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
<u>Chronic adults</u>	<u>OECD Test Guideline 245</u>	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	<u>Chapter 3.2.2 Table 3</u> <u>Chapter 3.3.2 Table 7</u> <u>Chapter 3.5.2</u> <u>Chapter 3.5.3</u>
<u>Larvae</u>	<u>OECD Guidance Document 239</u>	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	<u>Ef-values from tables X1a and X2a as appropriate for the relevant scenario</u>
<u>Exposure from surface water</u>	<u>Use highest PEC_{sw} from FOCUS step 1 or RAC for aquatic organisms.</u>	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	<u>SV-values from Tables Jx and Jy as appropriate for the relevant scenario</u>
<u>Exposure from puddle water</u>	<u>Use run-off PEC values from FOCUS</u>	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	<u>Ef values from Table X1c</u> <u>Chapter 9</u>

	<i>Guideline/test protocol</i>	<i>Implementation date</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
			Appendix S Chapter 6.1.2 and Appendix O
Accumulative risk assessment	Research still ongoing No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 8
Repeated exposure laboratory test on larval development beyond pupation of honeybees	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	
Screening step for assessment of exposure to residues in honeydew	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 3 and Chapter 9
Exposure from guttation fluid	More information is needed on which crops and under what circumstances guttation droplets are produced and to what extent guttation droplets are used as a water source	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees³⁰ June 2021	Chapter 3.5.1
Extrapolation rules for residue trials (minor crops, north-south, etc.)	[to be verified if necessary to maintain this line]	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees³⁰	

	<i>Guideline/test protocol</i>	<i>Implementation date</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i>
		June 2021	
Sublethal effects, HPG and other methods to address physiological effects, and effects on homing flight	More information is needed No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Appendix W
Risk from exposure to residues in succeeding crops	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	
Development of landscape-level exposure assessment criteria/methods	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 5.1.5

BUMBLEBEES

<i>Screening step spray applications</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Implementation date</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i> <i>Reference to the restructured EFSA GD</i>

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Acute adults	oral	ETR > 0.036 (bumble bee endpoint)	OECD Test Guideline 247	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees 30 June 2021	Chapter 3.2.2 Table 3 8.2.1.1 Appendix P	Formatted: Strikethrough
Acute adults	contact	HQ > 7 (downwards spray); HQ > 14 (upwards/sideways)	OECD Test Guideline 246	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees 30 June 2021	Chapter 3.2.1 Table 2	Formatted: Strikethrough
Screening step solid formulations		Trigger value	Guideline/test protocol	Implementation date	Reference to the EFSA Guidance Document of 4 July 2014 Reference to the restructured EFSA GD	Formatted: Strikethrough
Acute adults	oral	ETR > 0.036 (based on bumble bee endpoint)	OECD Test Guideline 247	To be used for applications submitted after publication of the revised EFSA Guidance Document on	Chapter 3.3.2. Table 7	Formatted: Strikethrough

			<u>the risk assessment for bees30 June 2021</u>	
Acute contact adults	HQ > 2.3 (based on bumble bee endpoint)	OECD Test Guideline 246	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021</u>	Chapter 3.3.1 <i>f_{dep}</i> from Table H1b
	<u>Trigger value</u>	<u>Guideline/test protocol</u>	<u>Implementation date</u>	<u>Reference to the EFSA Guidance Document of 4 July 2014</u>
Chronic toxicity	Based on honeybees end point. Reconsideration of safety factor needed.	<u>No protocols yet available</u>	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021</u>	Chapter 6.2.1
Risk to larvae	Based on honeybees end point. Reconsideration of safety factor needed.	<u>No protocols yet available</u>	<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for</u>	Chapter 6.2.1

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			bees 30 June 2021	
Higher tier studies			<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	
Study with micro-colonies			<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)
Semi-field and combined field-to-laboratory tests			<u>To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees</u>	Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)

SOLITARY BEES

	Trigger value	<i>Guideline/test protocol</i>	<i>Implementation date</i>	<i>Reference to the EFSA Guidance Document of 4 July 2014</i> Reference to the restructured EFSA GD
Acute contact		A ring test is currently and the test itself is ready to be implemented. However lack of guidance for higher tier testing.	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 6.3.1
Acute oral		A ring-test is currently ongoing but more work is needed regarding feeding of Osmia with a specific amount of food.	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 6.3.1
Chronic toxicity	Based on honeybees end point. Reconsideration of safety factor needed.	No protocols yet available.	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees 30 June 2021	Chapter 6.3.1

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Risk to larvae	Based on honeybees end point. Reconsideration of safety factor needed	No protocols yet available.	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021	Chapter 6.3.2.1
Semi-field and field test			To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 6.3.2.2 and 6.3.2.3

Part C

Further actions proposed in order to allow for full implementation of the EFSA Guidance Document.

- A review of the Guidance Document based on new scientific information and data.
- Reconsideration of background mortality and trigger values.
- Validation (cross-check) by using available higher tier data whether the level of conservatism introduced with current trigger values seems appropriate for different toxicity tests and exposure routes.
- Detailed definition of protection goals for bumble bees and solitary bees.
- Development of the following test:
 - Chronic oral toxicity test with bumble bees.
 - Larval toxicity test with bumble bees.
 - Accumulative toxicity risk assessment for bumble bees.
 - Field tests with bumble bees.
 - Chronic oral toxicity test with solitary bees.
 - Larval toxicity test with solitary bees.
 - Accumulative toxicity risk assessment for solitary bees.