This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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)

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:

- 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.
- 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: <u>www.efsa.europa.eu/efsajournal</u>.

Field Code Changed

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

Part A

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

HONEYBEES

| Screening step spray applications | Trigger value | Guideline/test protocol | Reference to the EFSA Guidance Document of | |
|--------------------------------------|--------------------------------------|------------------------------------|---|-----------------|
| | | | 4 July 2014 | |
| Acute contact | HQ > 42 (downwards spray); | OECD Test Guideline | Chapter 3.2.1 | |
| adults | HQ > 85 (upwards/sideways) | 214 | 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 | |
| | | 215 | 1010 5 | |
| Larvae | ETR > 0.2 | OECD Guidance | Chapter 3.2.2 | |
| | | Document 239 | Table 3 | |
| Exposure from | ETR_{acute} adults > 0.2; | Use highest PEC _{sw} from | Chapter 3.5.2 | |
| surface water | ETR _{chronic} adults > 0.03 | FOCUS step 1 or RAC | | |
| | ETR _{ehronic} larvae > 0.2 | for aquatic organisms. | | |
| Exposure from | $ETR_{acute} adults > 0.2;$ | Use run-off PEC values | Chapter | |
| puddle water | $ETR_{chronic}$ adults > 0.03 | from FOCUS | <u>3</u> 4.5.3 | |
| | ETR _{ehronic} larvae > 0.2 | | • | Formatted: Left |
| Exposure to plant | | | Chapter 3.6 | Formatted Table |
| <u>metabolites</u> | | | | |
| Concerning story - 1:1 | Tricconstant | Cuideline/test meters 1 | Defeneração | |
| Screening step solid formulations | Trigger value | Guideline/test protocol | Reference to the EFSA | |
| | | | Guidance | |
| | | | Document of | |
| | | | 4 July 2014 | |

| Acute contact adults | HQ >14 | OECD Test Guideline 214 | Chapter 3.3.1 f_{dep} 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 <u>.</u> 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 Formatted Table | |
| Refined risk assessment for exposure via nectar and pollen following spray applications | Trigger value | Guideline/test protocol | Reference to the EFSA Guidance Document of 4 July 2014 | |
| Refined exposure estimates ETR _{acute} ; ETR _{ehronie} ; ETR _{larvae} -for all <u>relevant</u> scenarios | ETR _{acute} > 0.2 ETR _{ehronie} > 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 | |

| Consider risk mitigation measures Consider further refinement of exposure estimate | | | relevant scenario 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 |
| Refined risk assessment for contact exposure following spray application | Trigger value | Guideline/test protocol | Reference to the EFSA Guidance Document of 4 July 2014 |
| 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 |
| Refined risk assessment for exposure via nectar and pollen | Trigger value | Guideline/test protocol | Reference to the EFSA Guidance Document of |

| following seed treatment or granule application applications | | | 4 July 2014 |
|---|--|---|---|
| Refined exposure estimates ETR _{acute} ; ETR _{chronic} ETR; ETR _{larvae} -for all <u>relevant</u> scenarios | ETR _{acute} > 0.2 ETR _{ehronic} > 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 |
| Refined risk assessment for contact exposure following seed treatment or granule application | Trigger value | Guideline/test protocol | Reference to the EFSA Guidance Document of 4 July 2014 |
| 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 |
| Consider further refinement of exposure estimate | | 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 |
| 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

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

| | Guideline/test protocol | Implementation date | Reference to the EFSA Guidance Document of 4 July 2014 |
|--|--|---|--|
| | | | <u>Appendix S</u> <u>Chapter 6.1.2</u> <u>and</u> <u>Appendix O</u> |
| 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 bees ³⁰ 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 | |

| | Guideline/test protocol | Implementation date | Reference to the EFSA Guidance Document of 4 July 2014 |
|--|--|---|--|
| | | 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

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

| Acute oral | ETR > 0.036 (bumble | OECD Test | To be used for | Chapter 3.2.2 | Formatted: Strikethrough |
|---|---|----------------------------|--|--|--------------------------|
| adults | bee endpoint) | Guideline 247 | applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021 | Table 3 8.2.1.1 Appendix P | |
| Acute contact adults | 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 bees30 June 2021 | Chapter 3.2.1 Table 2 | Formatted: Strikethrough |
| | | | | | |
| Screening step solid formulations | <i>Trigger value</i> | Guideline/test protocol | Implementation date | ReferencetotheEFSAGuidanceDocumentofJuly2014ReferencetotherestructuredEFSAEFSA | Formatted: Strikethrough |
| Acute oral adults | ETR > 0.036 (based on bumble bee endpoint) | OECD Test Guideline 247 | To be used forapplicationssubmitted afterpublication ofthe revisedEFSAGuidanceDocument on | Chapter 3.3.2. Table 7 | Formatted: Strikethrough |

| | | | the risk assessment for bees ³⁰ June 2021 | | |
|---------------------|---|---|--|---|--------------------------|
| Acute contact | HQ >2.3 (based on | OECD Test | To be used for | Chapter 3.3.1 | Formatted: Strikethrough |
| adults | bumble bee endpoint) | Guideline 246 | applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021 | <i>f_{dep}</i> from Table H1b | |
| | <u>Trigger value</u> | <u>Guideline/test</u> protocol | Implementation date | <u>Reference to</u> <u>the EFSA</u> <u>Guidance</u> <u>Document of 4</u> <u>July 2014</u> | Formatted: Strikethrough |
| Chronic toxicity | Based on honeybees end point. Reconsideration of safety factor needed. | <u>No protocols</u> <u>yet available</u> | To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021 | Chapter 6.2.1 | Formatted: Strikethrough |
| 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 | Chapter 6.2.1 | |

| Higher tier studies | | bees30 June 2021 To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees | |
|--|--|---|---|
| Study with micro- colonies | | To be used for applications submitted after publication of the revised <u>EFSA</u> <u>Guidance</u> <u>Document on</u> the risk assessment for <u>bees</u> | Chapter 6.2.2 and Appendix P (with possibility for applicants to modify) |
| Semi-field and combined field-to- laboratory tests | | To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees | Chapter 6.2.2 and Appendix P (with possibility for applicants to modify) |

SOLITARY BEES

| | Trigger value | Guideline/test | Implementation | <u>Reference to</u> | Formatted: Strikethrough |
|------------------|---|--|--|---|--------------------------|
| | | protocol | date | the EFSA Guidance Document of 4 July 2014Reference 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. | applications | 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. | applications | Chapter 6.3.1 | |
| Chronic toxicity | Based on honeybees end point. Reconsideration of safety factor needed. | <u>No protocols yet</u> <u>available.</u> | To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2021 | Chapter 6.3.1 | |

| honeybees end point. Reconsideration of safety factor needed available. applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees30 June 2024 6.3.2.1 Semi-field and field test and field test To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees 70 be used for applications submitted 1 year Chapter 6.3.2.2 and 6.3.2.3 | | | 1 | 1 | |
|---|----------------|-------------------|-------------------|--------------------|-------------|
| point. Reconsideration submitted after of safety factor needed file revised EFSA Guidance Document on the risk_assessment for bees30 June 2021 Semi-field and To be used for chapter field test To be used for after for submitted after publication of field test for field test Document on the risk_assessment for for bees To be used for for assessment for bees To be for applications submitted 1 year | Risk to larvae | Based on | No protocols yet | To be used for | |
| Reconsideration of safety factor needed publicationof therevised EFSA_Guidance Document on the risk_assessment for bees30_June 2021 Semi-field and field test To be used for applications submitted_after publicationof therevised EFSA_Guidance Document on the risk_assessment for bees_To-be usedfor applications submitted_1_year Chapter 6.3.2.2 and 6.3.2.3 | | honeybees end | <u>available.</u> | applications | 6.3.2.1 |
| of safety factor the revised needed EFSA Guidance Document on the risk assessment for bees30 June 2021 Semi-field and To be used for applications Chapter submitted after publication of 6.3.2.2 and publication of the revised EFSA Guidance Document on the risk assessment for best for after for publication of the revised effect EFSA Guidance Document on the for used for applications submitted 1 year | | point. | | submitted after | |
| needed EFSA_Guidance Document on the risk_assessment for bees30_June 2021 Semi-field and To be used for field test applications submitted_after publication_of the_revised EFSA_Guidance Document on the risk_assessment for bees_To_be used_for applications submitted_l year | | Reconsideration | | publication of | |
| Document on the risk_assessment for bees30_June 2021 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 Chapter 6.3.2.2 and 6.3.2.3 | | of safety factor | | the revised | |
| 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 Chapter 6.3.2.2 and 6.3.2.3 | | needed | | EFSA Guidance | |
| 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 Chapter 6.3.2.2 and 6.3.2.3 | | | | Document on the | |
| 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 Chapter 6.3.2.2 and 6.3.2.3 | | | | risk assessment | |
| Semi-field and field test To be used for applications Chapter Submitted after publication of the revised 6.3.2.2 and EFSA Guidance Document on the risk assessment for bees To be used for applications submitted 1 year for applications | | | | | |
| field test applications 6.3.2.2 and submitted after publication of 6.3.2.3 the revised EFSA Guidance Document on the risk risk assessment for bees used for applications submitted 1 year | | | | 2021 | |
| field test applications 6.3.2.2 and submitted after publication of 6.3.2.3 the revised EFSA Guidance Document on the risk risk assessment for bees used for applications submitted 1 year | | | | | |
| 6.3.2.3 submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees To be used for applications submitted 1 year | Semi-field and | | | To be used for | Chapter |
| publication of the revised EFSA Guidance Document on the risk assessment for bees To be used for applications submitted 1 year | field test | | | applications | 6.3.2.2 and |
| the revised EFSA Guidance Document on the risk risk assessment for be used for applications submitted 1 submitted 1 year | | | | submitted after | 6.3.2.3 |
| EFSA Guidance Document on the risk assessment for bees To be used for applications submitted 1 year | | | | publication of | |
| Document on the risk assessment for bees used for applications submitted submitted 1 | | | | the revised | |
| risk assessment for bees To be used for applications submitted 1 year | | | | EFSA Guidance | |
| for bees To be used for applications submitted 1 year | | | | Document on the | |
| used for applications submitted 1 year | | | | risk assessment | |
| applications submitted 1 year | | | | for bees To be | |
| submitted 1 year | | | | used for | |
| | | | | applications | |
| | | | | submitted 1 year | |
| after availability | | | | after availability | |
| of internationally | | | | of internationally | |
| agreed protocols | | | | agreed protocols | |
| | | | | - | |

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.
 - o Accumulative toxicity risk assessment for solitary bees.