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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

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DRAFT

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

COMMISSION STAFF WORKING DOCUMENT - DOES NOT NECESSARILY
REPRESENT THE VIEWS OF THE COMMISSION SERVICES

1. INTRODUCTION

The European Commission (EC) asked the European Food Safety Authority (EFSA) to develop a new Guidance Document on the risk assessment of plant protection products for bees. The Guidance Document, published on 4 July 2013, is intended to provide guidance for industry and national authorities in the context of the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009.

A large number of comments were submitted by Member States and stakeholders before and after the publication of the Guidance Document. Given the concerns raised, and the diverging views among Member States and different stakeholders, a workshop preceding the ‘take note’ process in the Standing Committee on the Food Chain and Animal Health was organised on 11- 12 December 2013. This workshop brought together risk managers and risk assessors from Member States to discuss technical issues as well as risk management and the possible implementation of the Guidance Document.

The workshop concluded that a full and immediate implementation is not possible because scientific methodology is not fully available in each area of the risk assessment. It was therefore proposed to establish a ‘roadmap’ for the implementation of the Guidance Document, and to decide which areas still need further development.

2. OBJECTIVE

With this implementation plan the Commission intends to define the path forward for the step-wise implementation of the Guidance Document on the risk assessment of plant protection products for bees. It lays down the time schedule for when testing methods have to be used and which data have to be requested by the responsible authorities from the applicants (see Appendix A). The implementation plan was finalised in cooperation with Member State Competent Authorities and the European Food Safety Authority (EFSA) and is based on agreements reached in a Working Group with experts from Member States and EFSA on 31 March 2014.

3. WORKING GROUP

The objective of the first meeting of the working group was to agree on the timeline for the implementation of different sections of the Guidance Document. The sections to be implemented on a short term will be applicable at the date from which the revised Guidance Document enters into force. A smaller steering group chaired by the Commission and supported by interested Member States is expected to contribute to the implementation of those sections that need further work and could be implemented on a medium or long term, as described below.

4. THE TASKS OF THE STEERING GROUP COULD INCLUDE E.G. THE PARTICIPATION IN MEETINGS OF OTHER GROUPS/ORGANISATIONS THAT ACTIVELY WORK WITH DEVELOPMENT OF TEST METHODS FOR HONEYBEES, BUMBLE BEES AND SOLITARY

BEES, TO COMMENT ON PROPOSED TEST PROTOCOLS AND TO FOLLOW THE SCIENTIFIC DEVELOPMENTS IN THE AREA. THE GROUP COULD ALSO SUPPORT THE HARMONISATION OF RISK ASSESSMENTS AND THE CREATION OF A SPECIFIC “INTEREST GROUP” ON CIRCABC WAS PROPOSED TO FACILITATE THIS. EFSA ON-GOING WORK

It was agreed in the Workshop held on 11-12 December 2013 that EFSA needed to restructure the guidance document to make it more user-friendly. This work is on-going and the new version of the document is expected to be finalised by 26 June 2014. Additionally, a calculator - a specific tool to facilitate the role of risk assessors who should apply the risk assessment schemes described in the Guidance - will be developed by EFSA and validated by Member State experts. Some of the short-cut values for herbicides will also be revised by EFSA. Following the publication, the revised Guidance Document is expected to be noted in the Standing Committee of the Food Chain and Animal Health and the date from which it will apply will be decided at that time.

5. TIMELINES

A step-wise implementation of the Guidance Document as described below has been agreed and applies to applications submitted from those dates:

- A. **Immediately** - 1 January 2015 for the chapters of the Guidance Document identified as applicable immediately.
 - B. **Medium term** - 1 January 2017 for areas identified as being possible to implement on a medium term (e.g. tests or risk assessment schemes which are under development but not yet suitable to be used).
 - C. **Long term** - areas for which more than 2 years of additional work is expected to be necessary before implementation.
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A. Applicable for applications submitted from 1 January 2015

HONEYBEES

<i>Screening step spray applications</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA GD 2013*</i>
Acute contact adults	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD 214	Chapter 3.1.2 Step 2(a)
Acute oral adults	ETR > 0.2	OECD 213	Chapter 3.1.2 Step 2(b)
Chronic adults	ETR > 0.03	Chronic 10-d oral toxicity test based on draft guideline (except HPG)	Chapter 3.1.2 Step 2(c)
Larvae	ETR > 0.2	OECD DRAFT GUIDANCE DOCUMENT Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure (under validation). Duration of the study: End of pupation	Chapter 3.1.2 Step 2(d)
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 4.2 of GD
Exposure from	ETR _{acute} adults > 0.2; ETR _{chronic}	Use run-off PEC values from FOCUS	Chapter 4.3 of GD

puddle water	adults > 0.03 ETR _{chronic} larvae > 0.2		
<i>Screening step solid formulations</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA GD 2013*</i>
Acute contact adults	HQ >14	OECD 214	Chapter 3.1.3 Step 3(a) of GD (<i>f_{dep}</i> to be aligned with GD on seed treatment)
Acute oral adults	ETR > 0.2	OECD 213	Chapter 3.1.3 Step 3(b) of GD
Chronic adults	ETR > 0.03	Chronic 10-d oral toxicity test based on draft guideline (except HPG)	Chapter 3.1.3 Step 3(c)
Larvae	ETR > 0.2	OECD DRAFT GUIDANCE DOCUMENT Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure (under validation). Duration of the study: End of pupation	Chapter 3.1.3 Step 3(d)
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 4.2 of GD
Exposure from	ETR _{acute} adults > 0.2; ETR _{chronic}	Use run-off PEC values from FOCUS	Chapter 4.3 of GD

puddle water	adults > 0.03 ETR _{chronic larvae} > 0.2		

* References will be updated after the revision of the Guidance Document.

<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 GD 2013*</i>
Refined exposure estimates ETR _{acute} ; ETR _{chronic} ; ETR _{larvae} for all <u>relevant scenarios</u>	ETR _{acute} > 0.2 ETR _{chronic} > 0.03 ETR _{larvae} > 0.2	OECD 213 Chronic 10-d oral toxicity test based on draft guideline (except HPG) Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test	SV-values from Appendix J, tables J4-J7 in GD
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 11 Appendix S

Semi-field and field effects studies		Based on EPPO 2010 and OECD 2007 with further details as provided in Appendix O	Chapter 1.8.2 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 GD 2013*</i>
Refined exposure estimate	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD 214	f_{dep} values from Appendix X of GD and guidance in Appendix N
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 11 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007	Chapter 1.8.2 and Appendix O
<i>Refined risk assessment for exposure via nectar and pollen following seed treatment or granule application applications</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA GD 2013*</i>

Refined exposure estimates ETR _{acute} ; ETR _{chronic} ETR; ETR _{larvae} for all <u>relevant</u> scenarios	ETR _{acute} > 0.2 ETR _{chronic} > 0.03 ETR _{larvae} > 0.2	OECD 213 Chronic 10-d oral toxicity test based on draft guideline (except HPG) Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test	Chapter 3.1.2 Step 5 SV-values from Appendix J, tables J4, J6 and J7 Ef values from Appendix X (needs to be aligned with seed treatment GD)
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 11 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007	Chapter 8.1.2 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 GD 2013*</i>
Refined exposure estimate	HQ >14	OECD 214	Chapter 3.1.2 Step 4 Appendix N
Consider risk mitigation			Chapter 11

measures Consider further refinement of exposure estimate			Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007	Chapter 8.1.2 and Appendix O

BUMBLE BEES

<i>Screening step spray applications</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA GD 2013*</i>
Acute oral adults	ETR > 0.036 (bumble bee endpoint)	OECD 213 (modified for bumble bees)	Chapter 3.2.2 Step 2(b) and 8.2.1.1 Appendix P
Acute contact adults	HQ > 7 (downwards spray); HQ > 14 (upwards/sideways)	OECD 214 (modified for bumble bees)	OECD 214/Chapter 3.2.2 Step 2(a) and 8.2.1.1 Appendix P
<i>Screening step solid formulations</i>	<i>Trigger value</i>	<i>Guideline/test protocol</i>	<i>Reference to the EFSA GD 2013*</i>
Acute oral adults	ETR > 0.036 (based on bumble bee endpoint)	OECD 213 (modified for bumble bees)	Chapter 3.2.2. Step 3(b) Appendix P (f_{dep} to be aligned with GD on seed treatment)
Acute contact adults	HQ > 2.3 (based on bumble bee endpoint)	OECD 214 (modified for bumble bees)	/Chapter 3.2.2 Step 3(a) Appendix P (f_{dep} to be aligned with GD on seed treatment)

Higher tier studies	<i>Guideline/Protocol</i>	<i>Reference to the EFSA GD 2013*</i>
Queenless micro-colonies		Appendix P of GD (with possibility for applicants to modify)
Semi-field and combined field-to-laboratory tests		Appendix P of GD (with possibility for applicants to modify)

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B. Medium term – Applicable for applications submitted from 1 January 2017

- Accumulative toxicity to honeybees. The hypotheses are complex and research is ongoing from which results could be taken into account on a medium term.
- Exposure of honeybees to plant metabolites.
- Repeated exposure laboratory test on larval development beyond pupation of honeybees. Further work is needed to include time to emergence in the test.
- Screening step for assessment of exposure to residues in honeydew.
- Exposure from guttation fluid. The assessment scheme as such is considered to be acceptable but 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. If providing water to honeybees is a possible risk mitigation measure should also be further discussed.
- Acute contact test for solitary bees. A ring-test will be conducted during 2014 and the test itself is ready to be implemented. However lack of guidance for higher tier testing suggests implementation on medium term.
- Acute oral test for solitary bees. A first ring-test will start in April 2014 but more work is needed regarding feeding of *Osmia* with a specific amount of food.
- Semi-field and field tests on solitary bees.
- Extrapolation rules for residue trials (minor crops, north-south, etc.)
- Honeybee sublethal effects, effects on hypopharyngeal gland or other test method to address physiological effects linked to colony-level effects.
- Honeybee effects on homing flight.
- Chronic toxicity to bumble bees based on the honeybee endpoint, reconsideration of safety factor.
- Risk to bumble bee larvae based on the honeybee endpoint, reconsideration of safety factor.
- Chronic toxicity to solitary bees based on the honeybee endpoint, reconsideration of safety factor.
- Risk to solitary bee larvae based on the honeybee endpoint, reconsideration of safety factor.
- Risk from exposure to residues in succeeding crops. Further guidance needed.
- Development of landscape-level exposure assessment criteria/methods

C. Implemented on a long term

- Revision of deposition factors based on an increased generic data set.
- 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
- Final definition of protection goals for bumble bees and solitary bees
- A revision of the Guidance Document based on new scientific information and data.