



Brussels, **XXX**
SANTE/10094/2015 Rev.1
(POOL/E4/2015/10094/10094R1-
EN.docx) D045385/06
[...](2019) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Regulation (EU) No 546/2011 as regards the assessment of the impact of plant
protection products on honeybees**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of XXX

amending Regulation (EU) No 546/2011 as regards the assessment of the impact of plant protection products on honeybees

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC¹, and in particular Article 78(1)(c) thereof,

Whereas:

- (1) Commission Regulation (EU) No 546/2011² lays down uniform principles for evaluation and authorisation of plant protection products, including for the assessment of the impact of plant protection products on honeybees.
- (2) It is necessary to modify those uniform principles for evaluation and authorisation of plant protection products in the light of the most recent developments in scientific and technical knowledge, in particular to provide uniform principles which consider different exposure routes in the assessment of contact toxicity to bees.
- (3) Regulation (EU) No 546/2011 should therefore be amended accordingly.
- (4) In order to allow Member States and interested parties sufficient time to prepare themselves to comply with the uniform principles for evaluation and authorisation of plant protection products as amended by this Regulation, it is appropriate to specify that it should not apply to applications submitted before the date of application of this Regulation or for applications for the renewal of an approval of an active substance for which the supplementary dossiers have been submitted before that date.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 546/2011

Part I of the Annex to Regulation (EU) No 546/2011 is amended as follows:

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).

(1) in section B, point 2.5.2.3. (b) is replaced by the following:

‘(b) This evaluation shall include:

- (i) the ratio between the maximum application rate expressed in grams of active substance per hectare and the contact LD₅₀ expressed in µg of active substance per bee (‘hazard quotient’) and the ratio between the estimated oral exposure (expressed in µg active substance per bee) and the acute oral LD₅₀ expressed in µg of active substance per bee (‘exposure/toxicity ratio’) and where necessary the persistence of residues on or, where relevant, in the treated plants;
- (ii) where relevant, the effects on honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product in accordance with the proposed conditions of use.’

(2) in section C, point 2.5.2.3. is replaced by the following:

‘2.5.2.3. Where there is a possibility of honeybees being exposed, no authorisation shall be granted if the hazard quotient exceeds or the exposure/toxicity ratio exceeds or is equal to any of the values indicated in the following table, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after the use of the plant protection product in accordance with the proposed conditions of use:

Acute oral toxicity (‘exposure/toxicity ratio’)		0.2
Acute contact toxicity (‘hazard quotient’)	downwards spray	42
	upwards and sideward spray	85
	solid formulations including granules and treated seeds	14

’.

Article 2

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2020.

However, this Regulation shall not apply to applications provided for in Articles 7(1), 33(1) and 43(1) of Regulation (EC) No 1107/2009 submitted before 1 January 2020.

Moreover, it shall not apply to applications provided for in Article 14(1) of Regulation (EC) No 1107/2009, for which the supplementary dossiers referred to in Article 6 of Commission Implementing Regulation (EU) No 844/2012³ are submitted before 1 January 2020.

³ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER