European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2019/2776(RPS)

14.10.2019

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) and (4)(c) of the Rules of Procedure

on the draft Commission regulation amending Regulation (EU) No 546/2011 as regards the assessment of the impact of plant protection products on honeybees
(D045385/06 – 2019/2776(RPS))

Committee on the Environment, Public Health and Food Safety

Members responsible: Bas Eickhout, Eric Andrieu, Martin Hojsík, Anja Hazekamp

B9-0000/2019

European Parliament resolution on the draft Commission regulation amending Regulation (EU) No 546/2011 as regards the assessment of the impact of plant protection products on honeybees
(D045385/06 – 2019/2776(RPS))

The European Parliament,

– having regard to the draft Commission regulation amending Regulation (EU) No 546/2011 as regards the assessment of the impact of plant protection products on honeybees (D045385/06),

– 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/EEC[1], and in particular Article 4, Article 78(1)(c), and point 3.8.3 of Annex II thereof,

- having regard to 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[2],

– having regard to Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market[3] and to Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market[4],

– having regard to the European Food Safety Authority (EFSA) Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) approved on 27 June 2013, and last updated on 4 July 2014[5](‘2013 EFSA bee guidance’),

– having regard Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[6],

– having regard to its resolution of 16 January 2019 on the Union’s authorisation

[1] OJ L 309, 24.11.2009, p. 1.
[2] OJ L 155, 11.6.2011, p. 127.
[3] *OJ L 93, 3.4.2013, p. 1.*
[4] OJ L 93, 3.4.2013, p. 85.
[5] 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, https://www.efsa.europa.eu/en/efsajournal/pub/3295.
[6] *OJ L 184, 17.07.1999, p. 23.*

procedure for pesticides[7],

– having regard to Rule 112(2) and (3), and (4)(c) of its Rules of Procedure,

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

A. whereas according to the Commission, there is a "*dramatic decline in the occurrence and diversity of all kinds of European wild insect pollinators, including wild bees, hoverflies, butterflies and moths. Numerous pollinator species are extinct or threatened with extinction*"[8];

B. whereas a scientific report by EFSA on the toxicity of pesticides showed that "*long-term toxicity may exceed predictions based on short-term tests by an order of magnitude*"[9];

C. whereas pursuant to Article 1(3) of Regulation (EC) No 1107/2009 the purpose of that Regulation is: *"to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production*";

D. whereas Article 4(1) of Regulation (EC) No 1107/2009 provides that "*An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3*";

E. whereas under point (e) of Article 4(3) of Regulation (EC) No 1107/2009 , a plant protection product *"shall have no unacceptable effects on the environment"*, and that particular regard must be had to certain considerations where the scientific methods accepted by the Authority to assess such effects are available, in particular the consideration of *"its impact on non-target species, including on the ongoing behaviour of those species*";

F. whereas under the second indent of point 3.8.3 of Annex II to Regulation (EC) No 1107/2009 an active substance, safener or synergist is to be approved *"only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist ... has no unacceptable acute or chronic effects on colony survival and*

[7] Texts adopted, P8_TA(2019)0023.
[8] Communication of 1 June 2018 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the EU Pollinators Initiative (COM(2018)0395.
[9] EFSA External Scientific Report on Chronic oral lethal and sub-lethal toxicities of different binary mixtures of pesticides and contaminants in bees (Apis mellifera, Osmia bicornis and Bombus terrestris), DOI: 10.2903/sp.efsa.2016.EN-1076, https://www.efsa.europa.eu/en/supporting/pub/en-1076.

development, taking into account effects on honeybee larvae and honeybee behaviour."

G. whereas Regulation (EC) No 1107/2009 thus went beyond the old Council Directive 91/414/EEC[10] by *inter alia* explicitly introducing express requirements with regard to the chronic effects of the use of an active substance, safener or synergist on colony survival and development;

H. whereas the data requirements for active substances as well as for plant protection products were modified in 2013 to include studies on the chronic effects of such substances and products on bees, as well as a study on the effects of such substances and products on honeybee development and other honeybee life stages[11];

I. whereas in 2013, EFSA updated the risk assessment methodology accordingly, *inter alia* taking into account chronic effects on bees as well as adverse effects on bumblebees and solitary bees;

J. whereas the updated risk assessment methodology was applied in the EFSA assessments of confirmatory data pursuant to Commission Implementing Regulation (EU) No 485/2013[12] with regard to three neonicotinoids, leading to near-complete restrictions in 2018[13];

K. whereas the 2013 EFSA bee guidance has, however, still not been formally endorsed by the Standing Committee established by Article 58 of Regulation (EC) No 178/2002 ('the Standing Committee');

L. whereas the Commission considers that it can only rely on the 2013 EFSA bee guidance for decisions in the context of ad hoc reviews of approval pursuant to Article 21 of Regulation (EC) No 1107/2009, but not for standard decisions on applications for approval or renewal, if it is not endorsed by Member States;

M. whereas the Commission tried to have the 2013 EFSA bee guidance implemented so that it could be applicable also for standard decisions on approval or renewal of active substances and (re-)authorisations of plant protection products;

[10] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p.1).
[11] Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013.
[12] Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (*OJ L 139, 25.5.2013, p. 12).*
[13] Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (OJ L 132, 30.5.2018, p. 31), Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35), and Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ L 132, 30.5.2018, p. 40).

N. whereas implementing the 2013 EFSA bee guidance can partly be done by amending the uniform principles laid down in Regulation (EU) No 546/2011;

O. whereas the Commission refrained however from doing so when in 2018, 16 Member States objected to implementing the 2013 EFSA bee guidance in the absence of a further review[14], in particular for the parts related to the assessment methodology for chronic risks;

P. whereas under Article 78(1)(c) of Regulation (EC) No 1107/2009, amendments to Regulation (EU) No 546/2011 are to take account of current scientific and technical knowledge;

Q. whereas recital 2 of the draft Commission regulation states that: "*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*";

R. whereas the draft Commission regulation however only introduces modifications indicated in the 2013 EFSA bee guidance with regard to acute toxicity to honeybees, but remains silent on chronic toxicity to honeybees, as well as on toxicity to bumble bees and solitary bees;

S. whereas the draft Commission regulation thus does not represent the most recent developments in scientific and technical knowledge, contrary to what is stated in recital 2 and contrary to the requirements in Article 78(1)(c) of Regulation (EC) No 1107/2009, in turn undermining the requirement in Article 4(1) of that Regulation to approve substances in light of current scientific and technical knowledge, which, thereby, also undermines the purpose provided for in Article 1(3) of that Regulation to achieve a high level of protection of animal health and the environment;

T. whereas according to EFSA, for a proper risk assessment of bees, it is important to consider acute toxicity, chronic toxicity as well as toxicity to larvae[15];

U. whereas it is of paramount importance that chronic toxicity and toxicity on larvae be assessed, in order to be able to address the risks posed by the new generation of systemic plant protection products, that lead to long-term chronic exposure, rather than short-term acute exposure;

V. whereas the changes proposed by the Commission in the draft regulation would only result in a refinement of the tests with regard to acute toxicity[16], which, according to an impact assessment by the pesticide industry, would not change the level of protection[17];

---

[14] See the summary record of the PAFF meeting of 23-24 October 2018 on https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20181023_ppl_sum.pdf.
[15] See 2013 EFSA bee guidance, p. 14.
[16] EFSA Technical Report on Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, doi: 10.2903/sp.efsa.2015.EN-924, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2015.EN-924, p. 44.
[17] Miles et al, 2018, Improving pesticide regulation by use of impact analyses: A case study for Bees: "possibly

W. whereas it is neither sufficient nor appropriate nor in line with the approval criteria of Regulation 1107/2009 to integrate the changes proposed by EFSA only with regard to acute toxicity in the draft Commission regulation;

X. whereas applicants have to submit relevant data on chronic toxicity pursuant to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013;

Y. whereas in the absence of any provisions with regard to chronic toxicity in Regulation (EU) No 546/2011, the Commission and Member States face difficulties as regards taking into account chronic effects of such substances and products on bees in their decisions on approval or authorisation;

Z. whereas this situation undermines the proper application of the approval criteria in Article 4 and in Annex II to Regulation (EC) No 1107/2009 with regard to bees, which in turn undermines the purpose of Regulation (EC) No 1107/2009, namely to achieve a high level of protection of animal health and the environment;

AA. whereas it is unacceptable that Member States oppose the full implementation of the 2013 EFSA bee guidance and thereby impede the proper application of the approval criteria with regard to bees;

BB. whereas such opposition is even more unacceptable in light of the fact that OECD test guidelines are available with regard to chronic toxicity tests for honeybees and effects on honeybee larvae (OECD test guidelines 245 and 239), and for acute toxicity tests for bumble bees (OECD test guidelines 246 and 247);

CC. whereas the Commission did not even submit a draft that would have corresponded to the 2013 EFSA bee guidance to the Standing Committee; whereas it thereby circumvented the obligation laid down in Article 5a(4) of Decision 1999/468/EC to submit a proposal to the Council, following which it could have adopted the measure as long as the Council did not oppose it by qualified majority;

DD. whereas it is highly regrettable that the Commission did not make use of its powers pursuant to Article 5a(2) of Decision 1999/468/EC and thereby effectively led to 16 Member States, that however did not form a qualified majority, being successful in impeding the proper application of the approval criteria with regard to bees;

EE. whereas the European Parliament in its resolution of 16 January 2019 considered that Regulation (EC) No 1107/2009 as such and its implementation need to be improved for it to achieve its purpose, and explicitly called on the Commission and the Member States to adopt without delay the updated bee guidance used by EFSA;

1. Opposes adoption of the draft Commission regulation;

2. Considers that the draft Commission regulation is not compatible with the aim and

---

there will be no overall significant changes in the risk assessment outcome for acute risk assessment for foliar applied products, i.e. the overall protection level is similar", pp. 87-88, https://www.researchgate.net/publication/326711149_Improving_pesticide_regulation_by_use_of_impact_analyses_A_case_study_for_bees.

the content of Regulation (EC) No 1107/2009;

3. Calls on the Commission to withdraw the draft regulation and submit a new one to the Standing Committee without delay;

4. Calls on the Commission to ensure that the new draft is based on the latest scientific and technical knowledge, and thus proposes modifying the uniform principles not only with regard to acute toxicity for honeybees, as in the current draft, but at least also with regard to chronic toxicity and larval toxicity for honeybees and acute toxicity for bumble bees, in particular given that OECD test guidelines are available for all of those parameters;

5. Calls on the Commission, if necessary, to make full use of its powers under Decision 1999/468/EC to obtain the submission of a proper proposal for scrutiny by the European Parliament and the Council;

6. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.