Follow up to the European Parliament non-legislative 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

1. **Resolution tabled pursuant to Rule 112(2), (3) and (4)(c) of the European Parliament's Rules of procedure**

2. **Reference numbers:** 2019/2776 (RSP) / B9-0149/2019 / P9_TA-PROV(2019)0041

3. **Date of adoption of the resolution:** 23 October 2019

4. **Competent Parliamentary Committee:** Committee on Environment, Public Health and Food Safety (ENVI), Internal market and Consumer Protection (IMCO), Agriculture and Rural Development (associated committees)

5. **Brief analysis/assessment of the resolution and requests made in it:**

The resolution refers to various provisions of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (**recitals C** to **F**) and the data requirements for application dossiers (**recital H**), the risk assessment methodology for bees updated by the European Food Safety Authority (EFSA) in 2013 and its use during assessment of confirmatory data for three neonicotinoids (**recitals I** and **J**), the efforts undertaken to get the updated guidance endorsed and the resistance by the Member States (**recitals K** to **O**), and the limitations of the draft regulation to only implement a part of the EFSA Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)[1] compared to what the European Parliament considers appropriate (**recitals R** and **T** to **Z**). The resolution notes that the regulation does not represent the most recent developments in scientific and technical knowledge (**recital S**), criticises the positions of the Member States and that the Commission has not made full use of its powers under the comitology procedure pursuant to Article 5a(2) of Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission (**recitals AA** to **AD**), and recalls the European Parliament's resolution of 16 January 2019 in which it called on the Commission and the Member States to adopt without delay the updated bee guidance from EFSA (**recital AE**).

The resolution opposes the draft Commission regulation (**paragraph 1**) and considers that it is not compatible with the aim and the content of Regulation (EC) No 1107/2009 (**paragraph 2**). The resolution calls on the Commission to withdraw the draft Commission regulation and submit a new one to the Standing Committee without delay (**paragraph 3**), and to ensure that the new draft 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 bumblebees as relevant test guidelines of the Organisation for Economic Co-operation and Development (OECD) are available (**paragraph 4**). Lastly, it calls on the Commission to make full use of its powers under Decision 1999/468/EC to obtain submission of a proper proposal for scrutiny by the European Parliament and Council (**paragraph 5**).

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[1] 'Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. And solitary bees)', EFSA Journal 2013;11(7):3295

6. Responses to requests and overview of actions taken, or intended to be taken, by the Commission:

Regarding **paragraph 2**, the Commission considers that the draft regulation is fully in line with the provisions laid down in Regulation (EC) No 1107/2009. It intends to modify the uniform principles with regard to the harmonised decision-making criteria related to the assessment of acute toxicity for honeybees, which the Member States have accepted to represent the best technical and scientific knowledge in line with the EFSA Bee Guidance Document from 2013. If adopted, the regulation would allow implementation of those parts of the EFSA Guidance related to acute risks for honeybees, in particular through the consideration of different exposure routes such as solid formulations, surface and puddle water and new requirements for higher tier (i.e. more refined) testing. This would result in a strengthened acute risk assessment for honeybees and a higher level of protection.

Further, the Commission affirms that the draft regulation is in line with the procedural steps set out in Council Decision 1999/468/EC on comitology and Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and that it is therefore within the implementing powers conferred on the Commission in that regulation. Moreover, the Standing Committee on Plants, Animals, Food and Feed has given a favourable opinion, and the Council has decided not to oppose it. Therefore, it represents the position of the majority of the Member States.

Concerning **paragraphs 3** and **4**, the Commission would like to recall that a clear majority of Member States have not accepted that the parts of the Bee Guidance Document related to chronic risks and risks to other pollinators represent the latest scientific and technical knowledge. Therefore, the Commission has asked EFSA to review the Bee Guidance Document to take account of new scientific knowledge that has emerged since 2013 in order to draw up guidance with the most up to date methodologies for conducting risk assessments for bees and other pollinators. The process is expected to be concluded in March 2021, which will enable the Commission to seek swift endorsement of the complete guidance, including the parts related to chronic toxicity to bees, and to bumblebees and solitary bees immediately thereafter.

The Commission also notes that while agreed test methods for acute toxicity to bumblebees and for the long-term toxicity honeybees and honey bee larvae are available, it is also necessary to agree on the interpretation of the results, which is the essential purpose of the Bee Guidance that is so far not accepted by the majority of the Member States.

Regarding **paragraph 5,** the Commission would like to recall that since 2013, the Commission has undertaken considerable efforts to obtain endorsement from the Member States on the EFSA Bee Guidance Document in the Standing Committee on Plants, Animals, Food and Feed. The comitology rules that apply to this Standing Committee oblige the Commission to endeavour to find solutions, which command the widest possible support within the Committee[2]. This is exactly what the Commission did, resulting in the favourable opinion obtained on 16 July (25 Member States in favour representing 71.91 % of the EU population, two abstaining and only one opposing).

In conclusion, the Commission regrets the European Parliament's objection to the draft regulation, and highlights that partial implementation of the EFSA guidance Document, which

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[2] Recital 13 of Regulation 182/2011 and Article 3(4), which apply also where the Committee acts under the Regulatory Procedure with Scrutiny and the respective standard rules of procedure (Article 4(5)) provide for the same obligation

would have strengthened the assessment of the acute risk to honeybees, cannot take place now. As the European Parliament's objection prevents the Commission from adopting the draft regulation, no part of the 2013 EFSA Bee Guidance Document can be implemented for the regular periodic reviews of approved active substances and the overall protection of bees cannot be improved.

The Commission intends to seek endorsement of comprehensive guidance, which will include, as requested by the European Parliament, measures related to chronic toxicity to bees, as well as effects on bumblebees and solitary bees. To this end, the Commission has mandated EFSA to review the Bee Guidance Document with a short timeline, taking fully into account new scientific knowledge that has emerged since 2013. This will enable comprehensive guidance with the most up-to-date methodologies for conducting risk assessments for bees leading to a higher level of protection. The Commission has tasked EFSA to closely involve Member State experts and stakeholders in the process in order to ensure that all views are duly taken into account. This should enable swift acceptance following the review.