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Commission proposals to further restrict the uses of Imidacloprid, Thiamethoxam and Clothianidin

Dear Dr Berend,

ECPA would like to share with you our concerns regarding the Commission's current proposals to ban all uses of three neonicotinoids with the exception of uses under permanent greenhouses. ECPA cannot support the Commission's proposals for the following reasons:

We believe that the current Commission proposals do not take into account the agronomic realities European farmers currently face. For many crops produced in the European Union, farmers currently do not have economically or environmentally viable alternatives. This was confirmed in the preliminary findings of an ANSES report¹. Furthermore, we are concerned that the Commission did not fully take into account all of the conclusions from the JRC's recent study², specifically the need for further study on the effectiveness and sustainability of possible alternatives.

The current proposals are based on a very conservative risk assessment, which does not properly take into account the various specific risk mitigation measures Member States could put in place. EFSA assessments identify several scenarios for which proper mitigation could be enforced in order to ensure a safe use of those substances by European farmers.

By taking sugar beet and the identified concerns on succeeding crops as an example, the Commission could propose a negative list of succeeding crops that farmers would not be able to cultivate the following year(s). On such example, it would be inconsistent with the concerns voiced by Commissioner Hogan, who has pointed out on several occasions that sugar beet should be exempted from the proposal³. Such conservative assessments⁴ are the results of using the EFSA Bee Guidance Document which is acknowledged to be overly conservative, unnecessarily precautionous, and impractical. This document still lacks approval from Member States. It is also now confirmed that its use since January 2016 has led to conclude unacceptable risks to bees for most pesticides⁵, including those used in organic agriculture. No further regulatory actions should be taken until Member States, EFSA and Commission can find agreement on an updated version.

I would also take the opportunity to refer to a letter dated 11 April 2018 from Commissioner Andriukaitis to Pekka Pesonen on behalf of the Agri-Food Chain RoundTable (attached for ease of reference). In this letter the Commissioner acknowledges a number of the issues we have set out above (including the

¹ ANSES, 5 March 2018. <https://www.anses.fr/fr/node/132967>

² *The impact of restrictions on neonicotinoid and fipronil insecticides on pest management in maize, oilseed rape and sunflower in eight European Union regions* <https://www.ncbi.nlm.nih.gov/pubmed/28842940>

³ European Parliament AGRI debate 28 February 2018 - Point on N. Erdos report on apiculture.

⁴ An Industry view on those assessment is provided in Annex to this letter

⁵ *EFSA conclusions issued since 1.1.2016 are using this guidance document: 54 active substances from which only 4 are concluded with acceptable risks to bees. 5 insecticides, 18 fungicides and 27 herbicides have either high risk/data gaps/non conclusion on risk assessment.*

lack of consideration given to alternatives and the fact that the guidance document is not approved), and which lead us to further question the decision to push ahead with a vote on this proposal at this point.

Regarding bee health, we would also like to emphasize that based on Bee health data collected by the European Commission or EFSA, there is no urgency to further restrict those substances. Existing data on honeybees in Europe show no decline and therefore do not confirm the supposed risks that the use of neonicotinoid insecticides cause to honeybees. We believe that the EFSA conclusions should be interpreted in light of these data. In addition, bee health is a multifactorial issue and all possible stressors should be considered together when discussing ways to improve Bee Health in Europe. We are ready to play our part in any initiative to bring together all stakeholders to address this in a coordinated and coherent way.

We would ask the Commission and Member States:

- To not vote on the current proposal
- To consider the availability, impact and effectiveness of possible alternatives
- To amend the current proposals to take into account scenarios in which risk managers consider the theoretical risk identified can be properly managed
- To initiate a working group with EFSA, Member States and interested stakeholders to work on a review of the EFSA Bee Guidance risk assessment methodology to take into account the numerous scientific progresses made over the last 5 years on bee testing and bee risk assessment and to avoid similar situation with any active substances.

We would be very pleased to discuss this issue further with you.

Yours sincerely

A handwritten signature in black ink, appearing to read 'P. J. Day'.

Peter Day
Director Regulatory Affairs

Annex 1

Analysis of the EFSA 2018 assessments for the three neonicotinoids

On [February 28, 2018](#), the European Food Safety Authority (EFSA) published three long-awaited reports concerning their bee risk assessment for the three neonicotinoids imidacloprid, clothianidin, and thiamethoxam as seed treatments and granules.

A conclusion of high risk was reached for only 5% of more than 500 scenarios based on data generated under field conditions of use. None of these cases involved honey bees. Yet, the results were [announced](#) as “Neonicotinoids: risks to bees confirmed”, and “Most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees, according to assessments published today by EFSA”.

In fact, where EFSA could draw a definitive risk conclusion from data generated under field conditions of use, **only low risks were found for honey bees**; additionally, while a high risk was found in 19% of the scenarios assessed for bumble bees, and in 1% of those assessed for solitary bees, risk was found to be low in the majority of cases.

One risk scenario that is repeatedly highlighted as a potential risk by EFSA is risk from succeeding crops, however, simple mitigation measures could be applied (e.g. only allowing bee unattractive crops to be sown in rotation) that would avoid exposure and remove this risk. So, what EFSA’s risk assessment conclusions really suggest is that **relatively few use patterns pose a clear high risk to bees even under the extremely conservative evaluation criteria of EFSA and in these cases mitigation, a common practice in the use of crop protection products, can avoid exposure.** At least most agricultural uses of these products should therefore be eligible for continued registration.

EFSA’s assessment follows the “Bee Guidance Document” which lays down an approach for carrying out a pollinator risk assessment. Several of its study requirements are not feasible due to a lack of validated study methods, which in turn impacts the outcome of an assessment: **in the absence of data or without clear confirmation of low risk EFSA’s conclusion will always be that there is a risk**; and this is the inherent flaw of the document. Applied consistently, this could result in a denial of registration for most crop protection products, including those used in organic agriculture. In light of this, the neonicotinoids actually stood up to the assessment fairly well – which is more in line with the outcomes of risk assessments from other highly regarded authorities

A full analysis is available at

http://www.ecpa.eu/sites/default/files/documents/Bayer_Report_on_recent_Neonic_conclusions_April_2018.pdf



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Mr Pekka Pesonen
Secretary General
Copa-Cogeca
61, rue de Trèves
B-1040 Brussels

Brussels, 11. 04. 2018
ARES(2018)

Dear Mr Pesonen,

Thank you for your letter on behalf of seven agri-food chain associations, dated 26 February 2018, in which you repeat the concerns from your letter of 11 December 2017 regarding the draft Implementing Regulations containing further restrictions of the use of three neonicotinoids (clothianidin, imidacloprid and thiamethoxam).

As indicated in my reply dated 10 January 2018 to that earlier letter, the survey of the Joint Research Centre (JRC) only assessed farmers' behavioural response to the restrictions and their perceptions of its effects. As correctly quoted in your letter, this survey does confirm that farmers changed their pest management strategies and generally relied on alternative seed treatment or other treatments. This survey never intended to assess the effectiveness or sustainability of these alternatives as specifically pointed out by the authors in the publication.

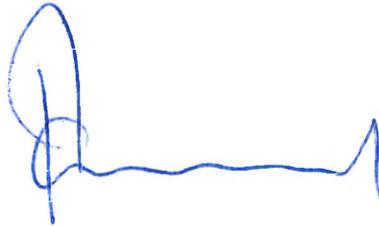
The survey by the JRC was not an official European Commission Impact Assessment or ex-post evaluation. In fact, Regulation (EC) No 1107/2009 does not include an impact assessment as part of the evaluation process. Therefore, the availability (or not) of alternatives to the neonicotinoids cannot be taken into account in the decision-making process.

The new Bee Guidance Document from the European Food Safety Authority (EFSA) represents the latest state of the science on risk assessment for bees and is a clear improvement compared to the earlier Guidance Document. So far, the new Guidance Document has only been used for the review

of the risk to bees for the substances clothianidin, imidacloprid, thiamethoxam and fipronil under Article 21 of Regulation (EC) No 1107/2009, which requires taking into account the latest scientific and technical knowledge. Later this year, my services will resume the discussions with the Member States on an implementation plan for the new Bee Guidance Document, with the view to achieve the necessary support for its endorsement.

I duly note the great concerns the proposals for further restrictions to the conditions of approval for the neonicotinoids raise for European farmers and assure you that we do take them carefully into account. Nevertheless, I would like to reiterate that the Commission pays the highest attention to the protection of bees and other pollinators considering their important role not only in nature but also for many cultivated crops. I trust that this is also the interest of Copa-Cogeca.

Yours sincerely,

A handwritten signature in blue ink, consisting of a large, stylized initial 'P' followed by a long, wavy horizontal line that ends in a small upward tick.