Mr Markos Kyprianou Commissioner of Health and

Consumer Protection
EUROPEAN COMMISSION
DG Health and Consumer

B-1049 BRUSSELS

Protection

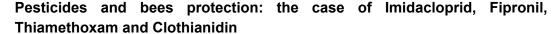
OPEN LETTER







N/réf.: CAT/JK/mcs/0611



Dear Commissioner,

The signatories of this letter are representatives of beekeeper associations, consumers and environmental organisations. Moved by the current situation of beekeeping in Europe, they wish to share with you their concerns about the approval, or possible approval, by your Directorate General and by the Standing Committee for Food Chain and Animal Health (SCFCAH) of some active substances used in Europe for phytosanitary aims.

On July 7th 2006, Directive 2006/41/EC has indeed included clothianidin in Appendix I of Directive 91/414/EEC, allowing Member States to authorize products containing this active substance. Thiamethoxam has recently been approved by the Standing Committee and is now awaiting the final decision of the Commission. In addition, the documents related to inclusion of imidacloprid and fipronil to Appendix I are currently available through the EFSA website. It is thus possible to access the Draft Assessment Report (DRA) for both of these substances, and for one of them, fipronil, the conclusions of the Peer Review on the risk assessment.

Various reasons lead us to believe that Europe should abandon the inclusion of these substances in Appendix I. Having considered the particular nature of these substances, we have indeed some doubts on the conformity of their evaluation reports to the clauses of Directive 91/414/EEC and its appendix.

These compounds share some characteristics that, according to the clauses of the directive, fall under the following categories:

1. These substances are systemic.

Systemic treatments, which aim to address the entire plant, are liable to contaminate all its parts, including the flower. It is proven today, and nobody denies it¹, that the aforesaid active substances are present in the nectar and the pollen of plants coming from treated seeds. Besides, this fact is not ignored in the DRA of imidacloprid and fipronil. These substances are thus found in the food of bees and their brood.



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See for example Chauzat et al., 2006: A survey of pesticides residues in pollen loads collected by honey bees in France, J. Econ. Entomol. 99 (2): 253 - 262; Rortais et alii, 2005: Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees, Apidologie 36 (2205), 71 – 83.

2. These substances are neurotoxic.

The aforementioned substances are insecticides that have the effect of blocking some mechanisms of neurotransmission in the adult insect or in the larva². In very small doses (of about one part per billion -ppb) these compounds are able, without killing the insect, to cause behavioural disturbances (e.g. orientation errors) that could be deadly for the colony, whose survival relies on the integrity of the ability of its members³.

3. These substances are persistent in the environment.

The documents appearing on the EFSA⁴ website state that worrying persistence occurs for imidacloprid and fipronil as well as for some of their metabolites. The same applies to clothianidin and thiamethoxam. This was somehow expected since the stability of these compounds is necessary for the systemic action supposed to last for the entire growing period of the plant, namely several months. As the pesticides are widely used and may be used on all cereals, maize, sugar beets, potatoes (as spray), as well as on beetroot, oilseed rapes or sunflower, for several consecutive years and in a systematic rotation, we believe it is necessary to study the behaviour of the substances in the soil after several successive years of treatment, and the possible contamination of untreated flowering crops that have been grown in a soil being treated for several consecutive years.

4. These substances carry acute toxicity that is extremely strong for bees.

Directive 91/414/EEC foresees this situation. In fact, it requires that Member States assess the hazard quotient (HQ) of phytosanitary compounds for bees before authorising them. The HQ is given by the dose of substance applied per hectare and the acute toxicity for bees⁵ due to oral intake or to contact. When the HQ is higher than 50, complementary tests have to be produced, in order to fully appreciate the effects (of the product) on honeybee larvae, on honeybee behaviour, colony survival and development after use of the plant protection product according to the proposed conditions of use ⁶.

The toxicity of these molecules for bees is significant⁷; in fact when the HQ is calculated, it reaches surprising figures: for example, for imidacloprid, HQ by oral acquisition reaches 40 540; while it gets to 1852 by contact. For clothianidin, HQ by oral intake scores more than 10,000°. For fipronil, HQs have not been calculated because they are considered not relevant – we will come back to this issue later. However, it is easy to calculate these quotients on the basis of the elements provided by the documents° and the values obtained through oral intake fall between 7,194 and 11,990 depending on the considered crop. The HQ figures that we could see for the

² Imidacloprid, clothianidin and thiamethoxam are neonicotinoids; as such they interfere with acetylcholine, a neurotransmitter fundamental to arthropods (and also important in vertebrates, including humana). As to fipronil, it acts on another neurotransmitter, GABA acid (gamma-acido-butyric).

See for example Colin et al.,, 2004: A method to quantify and analyse the foraging activity of honey bees: relevance to the sublethal effects induced by systemic insecticides, Arch. Environn. Contamin. Toxicol. 47, 387 – 395; also Suchail S., Guez D. and Blezunces L.P., 1999: Acute and chronic toxicity of Imidacloprid and its metabolites in Apis mellifera, 7th Bee protection symposium, Hazards of pesticides to bees, 7 – 9 September 1999.

⁴ Conclusion on the peer review of fipronil, pp; 23-27; Imidacloprid, Reasoned Statement of the overall conclusion, pp. 41-44.

⁵ HQ = Dose (of active matter in grams by hectare)/DL50 where DL50 is the amount of active matter killing half of the bees sample tested, in micrograms by bee.

Points 2.5.2.3 of parts B. Evaluation, and C. Decision-making processes, in Appendix VI of the Directive. This appendix is translated as such in the legislation of the Members States: none suppleness *what does this mean, it's not English* is allowed by the Directive about its transposition.

⁷ Values of the DL50 through oral way : fipronil : 4,17 nanograms by bee ; imidacloprid, 3,7 ng/ab : Clothianidin : 3,77ng/ab ; thiamethoxam : 5 ng/ab

⁸ Schmuck, R., et Keppler, J., 2003: Clothianidin – Ecotoxicological profile and risk assessment, Pflanzenschutz-Nachrichten Bayer, 56-2003, p. 31

⁹ Application rate of 30 or 50 g/ha according to the crop; DL50 of 4,17 ng/bee (cfr. Appendix B.9 in the Addendum 1 of the Draft Assessment Report, April 2006, version 4, p. 148); the HQ is the ratio between the first figure and the second one.

compounds presented are of the same order of magnitude. Required tests on bee brood have not been carried out. Tests on the colony, considered as a system, are insufficient.

In the imidacloprid and fipronil files, it is stated that HQ would not be a relevant index for seed coatings. On this point, we have the following remarks:

- This index, whether it is relevant or not, is the only one that appears in Appendix VI of Directive 91/414/EEC which requires these tests when the coefficient is greater than 50. Neither EFSA, nor the Members States have the liberty to decide whether to eliminate the measures¹⁰ that they consider irrelevant.
- Several scientific publications propose another safety index¹¹ for the products used to treat the seeds. If it appears that this coefficient is more relevant that the HQ, it is up to the Council to modify Appendix VI of the directive, in accordance with the article 18 of the directive. As long as the directive is not modified, the current version of the legislation must apply.
- It would indeed be unacceptable that some measures concerning bee protection appearing in the legislation be merely swept away because the safety coefficient is not relevant for seed coatings. Indeed, as we have seen above, seed coatings have an impact on bees, as the products in the coatings, on one hand, contaminate the bees and the reserves of the colony, and on the other are liable to seriously disturb bees behaviour, and thus to put in peril the survival of the colony, even at low doses.

Reading the reports brings up more remarks. The reliability of some results is questionable¹². In addition, conflicting scientific studies¹³ are available but not at all represented in the report. Therefore, we consider the risk assessment of these active substances insufficient, whilst many phytosanitary products based on these active substances are on the market and are used widely across the Member States.

For all the above mentioned reasons we ask that no molecule showing high toxicity (HQ>50) towards bees, and in particular, fipronil and imidacloprid, is registered in Appendix I of Directive 91/414/EEC as long as independent and validated tests have not shown the innocuousness of the product for bees, their brood, and the functioning of the colony considered as a system.

The Clothianidin and Thiamethoxam cases must be reassessed on this basis.

The registration of these molecules in Appendix I is unacceptable if the potential toxicity of the treatments by seed coating has not been accurately evaluated. Moreover, we note that Member States are currently not able to conform to the clauses of Appendix VI when authorising the products containing these active substances. Yet, it is up to the European authority to avoid any decision that would encourage Member States to act in violation of the rules that it has itself prescribed.

The European Commission has to earn more public credibility that it is committed to guarantee a high level of environmental protection to its citizens. Moreover, the future of our bees, valuable indicators of the state of the environment, fundamental components to our agriculture through their pollination services, and living organisms that we have the responsibility to protect, is extremely important.

¹⁰ Let us specify that, concerning the States, Appendix VI includes some 'evenly principles of evaluation' *this phrase makes no sense in English* retranscribed as such in the States legislations.

The ratio PEC on PNEC, where PEC = Predicted Exposure Concentration and PNEC = Predicted No Effect Concentration); see for example Halm *et al.*,, 2006, New risk assessment approach for systemic inscticides: the case of honey bees and imidacloprid, Environ. Sci. Technol., 40, 2448-2454

¹² For example, value of TER in the fipronil's evaluation: vol. 3, annexe B.9, addendum to DAR p. 162

¹³ cfr. footnote 3

We would greatly appreciate if you would meet with us in the near future to discuss these matters further.

We look forward to hearing from you soon.

Yours sincerely,

CC:

Stavros Dimas, Commissionner, Environment

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- Commission of Agriculture of the European Parliament
- Commission of Environment of the European Parliament
- The Members of the Standing Committee on the Food Chain and Animal Health