



European Beekeeping Coordination

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To: Mr. Vytenis Andriukaitis
European Commissioner for Health and Consumer Policy
European Commission
B-1049 Brussels

Louvain la Neuve, 1 September 2015

Subject: Pesticide authorisation and risks of bees

Dear Mr Andriukaitis,

I am writing you to complain about the latest authorisations of pesticide active ingredients, especially those of insecticidal nature, and to express my concern about the rationale that seems to be installed now in the authorisation procedure.

Bee Life welcomes the efforts and developments your services are undergoing to improve the situation of bees. However, we notice with great concern an increasing amount of cases in which the implementation of the safety principles established by Regulation (EC) 1107/2009 are not fulfilled.

The **authorisation of sulfoxaflor**, a fourth generation neonicotinoid, last 27th July 2015 through Commission Implementing Regulation (EU) 2015/1295 is a worrying case for two reasons:

- [On the one hand, the regulation acknowledges that *“It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. Those approval criteria are therefore deemed to be satisfied. It is therefore appropriate to approve sulfoxaflor”* (referral 7). However, the EFSA opinion on the risk assessment of sulfoxaflor¹ clearly states in paragraphs 3 of page 15 that the data and assessment available are considered insufficient to demonstrate the low risk of the field proposed, even considering risk mitigation measures. Therefore, the data gaps identified do not allow evaluating if approval criteria are satisfied. This fact renders the approval illegal;
- [on the other hand, article 6 of Regulation (EC) No 1107/2009 is advocated in the authorisation regulation arguing that *“[...] in the light of current scientific and technical knowledge, it is, however,*

¹ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor. EFSA Journal 2014;12(5):3692, 170 pp. doi:10.2903/j.efsa.2014.3692

necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information“ (recital 8). The confirmatory data required in Annexe I of the Implementing Regulation is not requested on the basis of new scientific and technical knowledge, either on sulfoxaflor's impact or exposure to bees or on risk assessment methodology. In the Draft Assessment Report (DAR) of sulfoxaflor, the EFSA reports adult mortality, behavioural problems and possible brood damage in the tunnel tests. In this situation and given that Article 4 of the Regulation (EC) No. 1107/2009 is not fulfilled, there are two options: (1) not authorised the active ingredient; (2) or request confirmatory data by risk assessors. As a result, Article 6 of the Regulation does not apply here. The data gaps were known and were not new. This fact again renders the authorisation illegal.

Secondly, Commission Implementing Regulation (EU) 1199/2013 **approved the insecticide chlorantraniliprole** from 1st may 2014. The EFSA described in the DAR that higher tier (tunnel) tests showed slight increase in adult mortality and I quote: “[...] Overall, the experts did not consider that the risk to bee brood could be regarded as low and therefore a data gap was identified. Signs of intoxication were reported in the semi-field bee brood study, although, no obvious effects were observed on the colony strength.” (paragraph 5 page 10). In other words, the risk of chlorantraniliprole on bee brood may either be medium or high but further studies are required to better evaluate the impact. Note that:

- [when studies show no risk to bees, risk assessors conclude that risk is negligible. On the contrary, when studies show (low, medium or high) risk, assessors conclude that the new data are required to conclude the absence of risk. This goes against the logic of Article 4 of Regulation (EC) 1107/2009 and the precautionary principle;
- [in the specific case of chlorantraniliprole the approval criteria established by Regulation (EC) 1107/2009 are not satisfied. Moreover, Commission Implementing Regulation (EU) 1199/2013 does not require any further studies or confirmatory information linked to bees. Chlorantraniliprole is therefore another active ingredient illegally authorised.

Finally, as you well know, Regulation (EC) 1107/2009 in application from the 14 June 2011 defines the criteria for approval and validation for the authorisation of pesticide in Europe (Annex I, point 3.8.3). Your services defined in 2013 (Commission Regulations (EU) 283/2013 and 284/2013) the data needed to evaluate if the pesticides or product fulfil these criteria and in application from 1 January 2014. Before this date, data requirements as in Annex II and III of the old Directive 91/414/EEC apply, respectively.

Therefore, active ingredients applying for re-/authorisation between 14 June 2011 and 1 January 2014 need to fulfil the new approval criteria but based on old data requirements. It is noteworthy that the list of data requirements defined by the regulation is much more complete than that of the annex of the Directive. As a result I assume there are a number of data gaps in these dossiers, namely as far as chronic effects, larvae mortality and honeybee behaviour.

Consequently, we hereby question the lawfulness of the authorisation of approval of sulfoxaflor, chlorantraniliprole and many more active ingredients applying for authorisation or re-authorisation (i.e. cyantilaniliprole and cyclaniliprole). You enable into the market pesticides following risk assessments that are not able to properly evaluate the impact they will have on bees. What is worse is that risk assessors know and state clearly in their DARs that assessment could be better, but it is not because they are not obliged by law to request other studies.

The problem is not new. We sent you already letters in the past pointing at this problem.

Bee Life has promoted among its members the participation to public consultations of these substances. We have continuously constructively contributed to the activities your services have initiated. It is frustrating to realise that these contributions seem not to be taken into account.

I find astonishing, and suffering from the consequences, enormously annoying and unacceptable, the fact that the Commission and member states keep putting the pollinators community at risk after the developments of the dossier in the later years. I am one of the 600.000 beekeepers in Europe that ensure the pollination of food and wild plants. I live from what bees produce as many of my colleagues who maintain the rural dynamism thanks to this profession. Your decisions and delayed reaction in the past have put me and my fellow colleagues in serious economic trouble, while You have the responsibility to ensure our safety and that of our animals and environment.

At this point I only request you the following:

1. Stop putting on the market active ingredients that are not well assessed, which you know there are not well assessed. This may be illegal, and immoral.
2. Start a serious monitoring of the pesticide environmental contamination. We have reiterated proposed to include pollen together with water as environmental analytical matrices. Please, make the outcome publicly available in a comprehensive European way.
3. On the basis of the results of environmental contamination, identify the cases of illegal uses of both authorised (i.e. application in crops where no authorisation exists) and non-authorised molecules and punish the polluters. Again, make the outcome of these punishments, both their frequency and location, publicly available.

You have all the tools in your hands to make a difference in the field. Please, make it real.

I very much look forward to your reply.

Best regards,



Francesco Panella
President of Bee Life European Beekeeping Coordination

Cc. Ladislav Miko, Michael Flüh (DG SANTE)