DECLINING EUROPEAN BEE HEALTH: BANNING THE NEONICOTINOIDS IS NOT THE ANSWER

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Introduction

The issue of declining bee health has been in the public eye for some time and it still remains unsolved. The cause of the decline is complex and there is no evidence pointing to a single cause. There are some organisations which push the concept that the decline in bee populations is due to pesticides, the main focus of which is currently the class of insecticides known as the neonicotinoids. There have been recent reviews of this class of insecticides by European Food Safety Agency (EFSA), which has resulted in a call for a European wide restriction of these pesticides by the European Commission (EC). This article is an analysis of these EFSA neonicotinoid reviews and the recent published EFSA scientific opinion and draft guidance for assessing effects of pesticides on bees, which were used as a basis for these reviews.

Unrealistic laboratory studies used to trigger concern

Academic papers published in 2012, in particular, Whitehorn *et al*.2012 and Henry *et al*. 2012a, which were also press released on the same day, reported potential sublethal impacts on bees exposed in the laboratory to neonicotinoid pesticides. Subsequent Media coverage and NGO pressure following these publications was probably a major factor leading to the EC requesting EFSA to review the approval of all of the neonicotinoids in light of available new scientific and technical knowledge. EFSA's subsequent evaluation of these studies (EFSA 2012a) identified shortcomings and questioned the relevance of the exposure conditions used, relative to exposure conditions under realistic field situations, and concluded more information was required. Although it may be widely assumed from reading the media releases that Henry's study showed colony collapses caused by neonicotinoids, they do not. His work observed behavioural effects and asserted that these could lead to colony collapse based on modeling of questionable validity (Cresswell & Thompson 2012). Indeed, Henry himself has acknowledged these criticisms and accepted that substantial improvement is needed before one could use honey bee colony modeling in its current form for risk assessment (Henry *et al*, 2012b).

Highly theoretical EFSA Science Opinion used for neonicotinoid review and new EFSA bee guidance document for plant protection products

EFSA reviewed the risk assessment for bees from the use of imidacloprid, clothianidin, and thiamethoxam as seed treatments and granular products on a variety of crops. This review was based on the "EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees", published in 2012 (EFSA 2012b). This opinion is also the current scientific basis for the development of a new EFSA "Guidance document on the risk assessment of Plant Protection Products on bees" (draft Guidance is still under review; EFSA 2012c), for use by notifiers and regulatory authorities in the context of the review and approval of plant protection products and their active substances under Regulation (EC) 1107/2009. This draft Guidance document proposes a tiered risk evaluation process moving from a very conservative tier 1 to increasingly refined higher-tier risk assessment steps requiring more field relevant data.

The first tier of this EFSA draft guidance for honey bees is very conservative eg European Crop Protection Association (ECPA) carried out an impact assessment which indicated that 95% of 150 products (equal amounts of insecticides, herbicides and fungicides) will fail the initial Hazard Quotient trigger value. For products that fail Tier 1 and then move to higher tier assessment requiring semi-field or field studies, the

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EFSA science opinion and draft guidance then dictates that 90th percentile exposure must be maintained in such studies. Whilst 90th percentile exposure can be maintained for semi-field studies where bees are held in tents over the treated crop, if a full field study is then triggered by such a semi-field study, then the 90th percentile exposure in this field study cannot be maintained as bees are free to forage anywhere in the landscape. As such, this would then lead to non-acceptance of the field study and the risk assessment being concluded using worst case semi-field tunnel studies, which do not represent realistic field conditions.

Furthermore, the EFSA draft guidance then demands that any field studies must demonstrate robust statistical power. As field studies are much less controlled than laboratory studies, the resulting field data will have increased variability, thus requiring increased replication to maintain statistical sensitivity and robustness. The true statistical replicate in field studies is not the individual hive but the field plot, which must be a minimum of 2 ha in size and separated from other treated and control plots and from other attractive fields or forage by at least 2 km. Consequently, the number of replicate plots required to provide such robust statistical power will effectively preclude the conduct of such field studies in the future, as they will not be able to meet this guidance. As a result, a higher-tier risk assessment tool, which provides invaluable information on the risk to bees under realistic field conditions, will be lost. When a very conservative first tier risk assessment scheme is combined with higher-tier semi-field options, where worst case exposure must be maintained, and where no validated field study design is available which meet the EFSA guidance conditions, then industry and regulatory authorities are left with a dysfunctional regulatory risk assessment scheme. Under this EFSA scheme, all insecticides and many fungicides can never pass. The finalization of this new EFSA bee guidance document has been delayed, in order to allow EFSA to consider over 1000 comments received during the commenting period. The volume of comments and the resulting delay clearly shows that the EFSA's precautionary and theoretical approach on bee risk assessment is still very far from being accepted by the academic and regulatory community. Nevertheless, EFSA used the approach outlined in this guidance for the recent neonicotinoid reviews to assess and ultimately disqualify the large body of higher tier field studies conducted in the last decade.

For bumble bees and solitary bees, the first tier is even more conservative than for honeybees. This situation is compounded by the fact that there are no validated study guideline options available, particularly for higher tier studies. Consequently, there are no options to refine and improve the outcome of a conservative Tier 1 regulatory risk assessment. Once again it will be almost impossible for any insecticide to be registered under such a scheme rendering it dysfunctional. Clearly, further higher-tier study options must be developed and validated for bumble bees and solitary bees before the proposed conservative first tier scheme can be implemented.

EFSA conduct highly critical and conservative reviews of Neonicotinoids

In the EFSA neonicotinoid reviews, risk assessments were conducted for exposure to dust and systemic residues in nectar, pollen and guttation droplets. In addition, exposure via honeydew, systemic residues from succeeding crops, and the risk to non-*Apis* pollinators were also assessed. When measured against the conservative science standards set out in the "EFSA Science Opinion (EFSA 2012b) and described above, there were data gaps identified for nearly all registered uses, since none of the higher tier studies conducted so far, which demonstrated safe use, were found to meet the new theoretical science standards. It is both scientifically and procedurally wrong to claim these as data gaps since the science standards used for these neonicotioid reviews and the current draft of the new EFSA bee guidance document (EFSA 2012c), are new, still under review and considered quite controversial. The large number of data gaps identified in the EFSA review incorrectly give a perception that industry has been negligent and ignored risk, when in fact the industry has been working closely with Member State (MS) authorities to address any new risks identified, fill any data gaps and comply with requests that authorities have made.

For each of the neonicotinoids review reports EFSA highlighted specific risk areas. For example for thiamethoxam, the areas of concern identified were:

"A high acute risk to honey bees was identified from exposure via dust drift for the authorised uses in cereals, cotton, oilseed rape (except for uses with the lowest application rate authorised in the EU) and maize. A high acute risk was also identified for exposure via guttation fluid for the authorised uses in maize" (EFSA 2012e).

Whilst for clothianadin, the areas of concern identified were:

"A high acute risk to honey bees was identified from exposure via dust drift for the seed treatment uses in maize, oilseed rape and cereals. A high acute risk was also identified from exposure via residues in nectar and/or pollen for the uses in oilseed rape (EFSA, 2012f).

However, EFSA chose in their press release to ignore these product specific differences and identify risks collectively for all 3 neonicotinoids as follows:

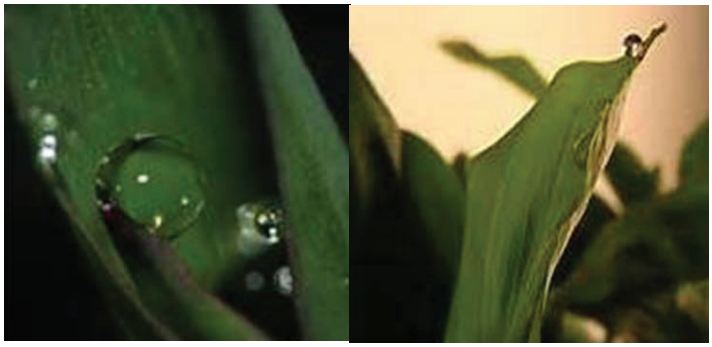
For dust exposure from seed treatment products, risks are concluded for cereals, cotton, maize, sunflower and oilseed rape. Data gaps were considered in other crops and only sugar beet was considered safe.

Risk was identified from systemic residues in nectar and pollen for all flowering, bee-attractive crops.

Risk was identified from residues in guttation water for all uses in all crops.

EFSA suggest that only limited information is available for non-*Apis* pollinators, honeydew as an exposure pathway, and systemic residues in succeeding crops; therefore data gaps are concluded here for all uses.

This EFSA Press release document was the only document which provided the common conclusions from the review of the 3 neonicotinoids, making it the most relevant and potentially influential document in setting the general direction for interpretation of the results eg by EC. By ignoring these product specific differences in their press release, EFSA effectively provided incorrect information and exaggerated the risks identified for each of the 3 neonicotinoids individually. For example, a risk from systemic residues in pollen and nectar was not highlighted as a critical area of concern in the EFSA review of thiamethoxam, contrary to the press release conclusion above.



Flaws in the EFSA risk assessment conclusions using Thiamethoxam review (EFSA 2012e) as an example

Risk from dust

For the dust risk assessment EFSA discounted risk mitigation measures and progress related to seed treatment quality and sowing machinery, which are already successfully in place at MS level. One example are the compulsory dust limits for treated seed and use of dust deflectors on seed drills in France, which have been shown to substantially reduce dust during drilling.

Data from key monitoring projects, which confirmed low risk to bees under real in use conditions, were again not accepted. One example is a thiamethoxam seed treated maize monitoring program carried out between 2008 and 2011 by the French regulatory authority. This study confirmed that when deflectors were used on seed drill machinery, in combination with a dust limit on treated seeds, there were no effects on honeybees reported following the drilling of thiamethoxam treated maize.

For oilseed rape (OSR) and cereals seeds, EFSA used the worst case dust deposition values based on the pneumatic drilling of thiamethoxam treated seeds. This resulted in EFSA concluding that dust exposure represented a high acute risk to bees for those treated crops. However, EFSA incorrectly ignored that in many countries these crops are predominantly drilled mechanically, which is generally associated with significantly lower dust deposition than pneumatic drilling (Fent, 2011). If EFSA had used the appropriate mechanical dust deposition values for those crops then a low acute risk to bees from dust exposure would have been concluded.

The potential dust risks identified by EFSA from thiamethoxam treated OSR were also based on the highest sowing rates used in EU giving a maximum application rate used by EFSA in their assessment for OSR of 33 g a.s./ha. EFSA partially acknowledge this in their conclusion phrasing for thiamethoxam as follows: "A high acute risk to honey bees was identified from exposure via dust drift for the authorised uses in … oilseed rape *(except for uses with the lowest application rate authorised in the EU)"*. However, this conclusion is still misleading since the majority of OSR seed is actually drilled at the lower application rates. In their assessment, EFSA used a maximum seed sowing rate of 8 kg seed /ha compared to the predominant sowing rate of 4 kg seed/ha. If this much more typical sowing rate of 4 kg seed/ha is used then the resulting application rates for use in the risk assessments would be between 8–16.8 g a.s./ha (compared to 33 g a.s./ha used by EFSA), and an acute risk to bees from dust would not be concluded.

Risk from guttation

EFSA has incorrectly identified an acute risk to bees from exposure to guttation from thiamethoxam treated maize seeds. Although residue levels of thiamethoxam in guttation droplets are high during the first 3–4 weeks following the emergence of the plant from the ground, at this early stage of development, maize is not flowering and there is no food source on the field. The crop is therefore unattractive to honeybees and the vast majority of bees would be highly unlikely to enter the crop.

Guttation droplets are not a significant source of water for bees. In fact, EFSA has overstated this significance because there are better and more reliable sources of water for honeybees in the landscape (Pistorius *et al*, 2012). In addition, guttation droplets predominantly occur during periods of low honeybee flight activity, (e.g. during the early morning).

EFSA has ignored the best available and recent science on risk to bees from guttation. For example, a recently published International Committee on Plant Bee Relationships (ICPBR) guttation paper (Pistorius *et al*, 2012) and literature review on neonicotinoid and bees (Thompson *et al*, 2012) concluded a low risk to honeybees from guttation droplets from neonicotinoid seed treated crops. It also should be noted that a new study, conducted by the State Institute of Beekeeping at the University of Hohenheim and the Julius Kühn Institute has also concluded that guttation from another crop, e.g. OSR, grown with seed treated with neonicotinoid insecticides, shows no unacceptable risk to honeybees (Specht, 2013).

Syngenta has just completed an additional extensive field testing program on thiamethoxam seed treated maize in France, which was unavailable to EFSA at the time of the thiamethoxam review. This field program investigated 19 treated sites and 3 control sites and reported no adverse effects on honeybee colonies from potential exposure to both dust during drilling and exposure to guttation (Kriznan, 2012 unpublished report).

Risk from systemic residues in pollen & nectar

EFSA discounted key higher-tier field data because of suggested weaknesses in the existing field study guidelines as prescribed in the EFSA Opinion on the Science behind bee risk

assessment for pesticides (EFSA 2012b). Indeed the new draft EFSA guidance proposal for bee field studies (EFSA 2012c), which was based on this same EFSA Science Opinion, has been heavily criticised during the public consultation period. One example of a field study where the results were not accepted by EFSA, was a comprehensive field study program, which investigated 4 consecutive years of exposure of bees to nectar and pollen from flowering OSR and maize seed treated with thiamethoxam. This study showed no adverse effects on honeybee colonies including during the sensitive over-wintering phase. These field data better reflect the potential risk to honey bees in practice than laboratory studies which use unrealistic exposure conditions. It is worth noting that in the Pesticides Peer Review Meeting (EFSA 2012e) where the review of thiamethoxam was first considered by Member States, the following statement about this field program was captured in the minutes: "A key point which the experts noted is that the studies were of excellent quality and really made a great effort to scientifically understand the potential long-term effects on the colony due to exposure of thiamethoxam. The studies are some of the most detailed and comprehensive that the experts had seen used for regulatory risk assessment." Yet for these specific field trials, EFSA still concluded that uncertainties remained and that "*a low long-term risk to honey bee colonies cannot be concluded*" (EFSA, 2012d).

Since the publication of this EFSA evaluation there has been a new paper recently published which supports low risk to bees from systemic exposure to pollen and nectar from neonicotinoids (including thiamethoxam) treated oilseed rape. i.e. No adverse effects were reported on bee mortality, brood development, strength, and honey yield (Pohorecka, *et al*, 2012).

Evidence analysis used by EFSA is inconsistent in its application

The most serious weakness of the review is that most of the existing evidence from available higher-tier field studies has been rejected as unusable in risk assessment. Similarly, extensive monitoring studies at Member State level are also poorly included. This review demonstrates a bias in the standard of proof required. Evidence of potential harm seems to be easily accepted, whilst evidence of safety is subject to deep scrutiny. So even though there is a large body of semi-field and field work that shows no impact on long term health and survival of honeybee colonies, this is poorly accounted for in the risk assessment or entirely excluded, even where EFSA acknowledge the work to be of a high quality.

EFSA and EC failed to acknowledge other factors affecting bee health

There is a growing published evidence base that supports the fact that there are a number of other important factors affecting bee health, in particular bee pests and bee diseases, but also including habitat loss, quality and quantity of available forage, and bee keeping practice. Indeed, a recent survey analysis of both beekeepers and bee laboratories published by the European Commission itself, reported that bee pest and diseases were the dominant perceived concern for bee health (blue bars in Figures 1 &2), with pesticides well down the relative priority list (grey bars in Figures 1 & 2).

A number of pests and diseases to which honey bees are susceptible, have been demonstrated as being implicated with colony losses. The major pests/diseases are the parasitic mite *Varroa destructor*, American foulbrood (*Paenibacillus larvae* ssp. *larvae*), European foulbrood (*Nosema* spp.), honey bee viruses, and the Acarine mite (*Acarapis woodi*) (Thompson & Wilkins, 2012). *V. destructor* is present in virtually every colony in Europe. In the absence of effective treatments, colonies normally die, with a steep decline in the adult bee population until only a few bees and the queen remains. This varroa mite is also an important vector of a number of viruses which affect honey bee health and shorten the lives of infected bees under certain conditions. There are a large number of viruses associated with honeybees (at least 18), but until the introduction of *V. destructor* they were generally considered harmless. It appears that *V. destructor* acts as both a disseminator and activator of a number of viruses. The presence of Deformed Wing Virus (DWV) is often associated with *V. destructor* infestation, and the role of *V. destructor* in transmission and activation of this virus has already been experimentally demonstrated (Nazzi *et al* 2012; Martin *et al*, 2012). DWV is one the most widespread bee viruses in Europe and is now considered one of the key players in colony collapse in Europe (Thompson & Wilkins, 2012).

Evidence also suggests that a drop in managed honey bee colonies in Europe may simply be linked to a decline in beekeeping. The number of beekeeper-managed colonies rose between

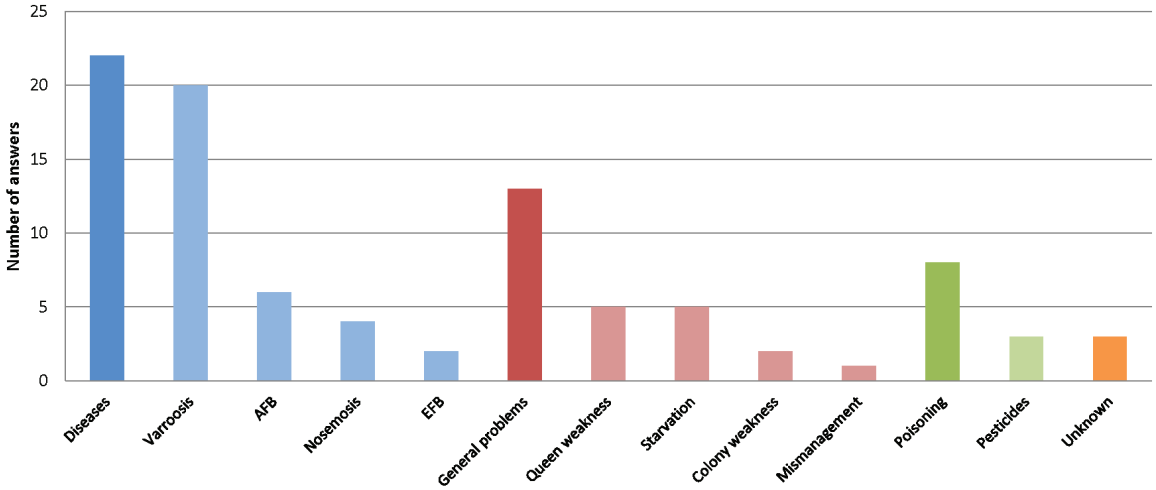


Figure 1. European Union Reference Laboratory Survey of main causes of colony mortality reported by bee keepers.
Source: *http://www.ebcd.org/en/EP_Intergroup_CCBSD/Agriculture/Bee_Health_in_Europe.html.*

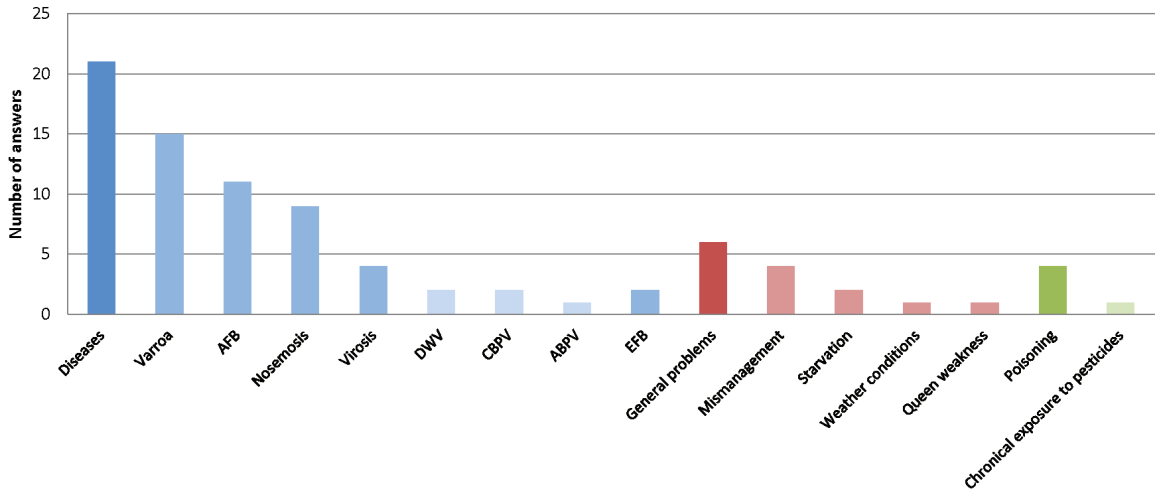


Figure 2. European Union Reference Laboratory Survey of main causes of colony mortality reported by the laboratories.
Source: *http://www.ebcd.org/en/EP_Intergroup_CCBSD/Agriculture/Bee_Health_in_Europe.html.*

1965 and 2005 in Southern Europe, especially in Greece, Italy and Portugal, and declined in Central and Western Europe. This may be because beekeeping in Europe is widely considered unprofitable when carried out on a small scale as a hobby or secondary activity.

Conclusion

As a result of some highly publicized laboratory studies in 2012, the EC urgently commissioned EFSA to review the risk to bees from the neonicotinoids. EFSA were given a narrow mandate and the time available to complete the reviews was extremely limited. Indeed, by the time the mandate was finalized EFSA had just a few months to complete the reviews in order to meet the EC deadline. Consequently, EFSA were pushed into taking an extremely critical and highly conservative approach in their review, identifying a long list of potential data gaps and risks to bees. However, several important flaws can be identified in some of the specific risk assessments carried out (e.g. for dust and guttation), in the general methodology used (e.g. virtually discounting all field studies and weight of evidence) and the fact that the science based approach used is not yet agreed or adopted within EU, and indeed is considered very controversial by the scientific and regulatory community. As a result the EC has proposed a severe EU wide restriction on the use of the neonicotinoids as seed treatments, soil applications and foliar treatments, even though the foliar uses have not yet been reviewed by EFSA or the MSs.

These restrictions must also be considered in light of the recent Humboldt Forum study (www.neonicreport.com), which concluded that neonicotinoid pesticides make an enormous socio-economic and environmental contribution to European agriculture and the wider economy. Neonicotinoid seed treatments are the most advanced crop protection solutions available for the targeted control of extraordinarily damaging pests. Neonicotinoids are applied with dose rates typically 10–20 times lower than the best available alterna-

tives and prevent crop losses resulting in up to 40% reduction in yield. Without these products an additional 3 million hectares of land outside Europe will need to be brought into production adding an environmental burden of 600 million tons of CO_2 (Noleppa & Hahn, 2013).

It is clear that we need healthy and thriving bee populations. The sustainability of agriculture depends on this. But we also need safe, modern, and innovative pesticides like the neonicotinoids if we are to produce the food we need. Rather than focusing on potential theoretical risks to bees under worst case unrealistic conditions from pesticides, we need to develop regulatory risk assessment guidance that enables in-use field realistic assessment approaches. In this way products and practices can be developed that allow bees and pesticides to co-exist together in a sustainable agricultural production system.

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