[redacted]

From: [redacted]
Sent: 24 January 2013 22:46
To: PS/Owen Paterson (Secretariat)
Cc: PS.Advisers (Secretariat)
Subject: Syngenta - letter re: neonicotinoids - ahead of EU Agriculture Council - 28 Jan

CCU
POST ROOM

Please find attached a letter to the Secretary of State from [redacted] ahead of the EU Agriculture Council meeting in Brussels on Monday 28th January.

In addition, I attach supporting documentation relating to the points set out in the letter.

A confirmation that this letter and supporting materials have been received and considered would be appreciated.

Regards,

[redacted]

Syngenta
Jealott's Hill International Research Centre
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[redacted]

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January 24, 2013

Dear Secretary of State,

The EU Agriculture Council will discuss the EFSA Report on the risk posed to bees by neonicotinoid pesticides on Monday January 28th 2013. At least one Member State is pushing for an immediate restriction. I strongly urge the UK to block this attempt and allow a full consideration of the EFSA report, including the response of Syngenta, which I enclose with this letter.

EFSA's conclusion on our own neonicotinoid pesticide – thiamethoxam – provides no grounds for a restriction. Their review was underpinned by a scientific opinion which one Member State, Germany, argued was "not fit for risk assessment purposes". Consequently, the risks that EFSA did identify (e.g. for dust drift, guttation, and residues in pollen & nectar) are highly theoretical.

Furthermore, extensive field studies and independent monitoring demonstrate that these risks do not have an impact on the health of bee colonies. Without sound justification, most of these studies and independent monitoring data were ignored. In fairness to EFSA, they have at least conceded that their latest evaluation contains "a high degree of uncertainty".

You will know that neonicotinoid pesticides used as seed treatment contain levels of active ingredient up to 50 times lower than other alternatives. The irony is that should this technology be restricted farmers would produce less using more pesticide without improving bee health.

Nevertheless, the European Commission may provide the Agriculture Council with a proposal for a restriction, which is not justified by the report. This would cost the UK farming industries up to £630 million per year with winter wheat and oilseed rape growers in particular facing yield reductions of more than 20%.

Syngenta invests approximately £250 million annually in the UK in R&D, manufacturing, and our commercial organizations employing more than 2,000 people. We do this because of the Government's strong support for technology in agriculture and an evidence based approach to regulation. I therefore call on you to resist any attempt to force a quick decision on restricting this technology and instead to allow for full consideration of the EFSA report and the response of the companies concerned.

I remain at your disposal should you have any questions.

Yours sincerely,

EFSA review of the risk to bees from thiamethoxam

Response by Syngenta to the European Commission

Overview

Syngenta believes that the European Food Safety Agency (EFSA) report on the risks allegedly posed to bees by thiamethoxam provides ***no grounds for a restriction or ban*** *on this technology which is vital for sustainable agriculture in Europe.*

It is important that this review is first put in context given the wide body of available evidence which points to ***loss of habitat and nutrition and the devastating impact of the varroa mite*** *(& the diseases it transmits) as the primary causes of the decline in bee health. There are very few experts in this field who believe that neonicotinoid pesticides are responsible for declines in bee health but the narrow remit of the efsa review risks creating an impression that a restriction on the technology would solve the problem.*

Furthermore, ***Neonicotinoid seed treatment, in particular, is one of the most advanced crop protection solutions available*** *for the targeted control of extraordinarily damaging pests. Thiamethoxam in particular is applied with dose rates typically 10-20 times lower (in some cases 50 times lower) than the best available alternatives and prevent crop losses of up to 40% of the yield. The irony is that* ***should this technology be restricted farmers would produce less using more pesticide****.*

The ***methodology used by efsa to conduct the review was questionable*** *because it was based on* ***a highly theoretical and extremely conservative scientific opinion*** *which is also being used to draft a new guidance document on the risk assessment for plant protection products and bees. This document is proving to be highly controversial because it would make it impossible to maintain the registration of any existing insecticides and prevent new ones from being brought to the market. Several member states have made strong challenges against the guidance document and the underlying scientific opinion developed by efsa.*

This scientific opinion led to ***the identification of risks to bees from thiamethoxam which are highly theoretical and based on unrealistic worst case scenarios****. This has been compounded by efsa's limited practical knowledge of agriculture, which was clearly illustrated by their inability to differentiate between crops sown by pneumatic drilling and those done mechanically.*

The ***review ignored key studies and field monitoring data****, much of it conducted by Member State authorities, which prove the safe use of thiamethoxam on millions of hectares of European crops for over ten years. These* ***omissions ensured that the efsa review is highly theoretical and detached from the reality of farming practices****.*

In addition, many of the data gaps identified by efsa only emerge because of new and unrealistically precautionary requirements proposed in the draft efsa guidance document for bee risk assessment which is contested by member states and neither approved nor implemented. ***Syngenta had no way of anticipating these new requirements*** *which in any case may not be included in the final version of the risk guidance document.*

Given all this, Syngenta notes that Efsa itself acknowledges that ***"there is a high level of uncertainty in the latest evaluation"***[1]*.which makes the inflammatory press release used by the Agency to publish its conclusions all the more disappointing and unacceptable.*

1. Bee health declines: putting the alleged role of pesticides in context

It is important to start our response by putting the efsa review of the alleged risks posed to bee health by neonicotinoid pesticides into a broader context. Few in the scientific world believe that neonicotinoid pesticides play a role in the decline in bee health and instead point to the growing published evidence base that shows that the primary factors affecting bee health in Europe are the loss of habitat and nutrition and bee pests and diseases, such as Varroa destructor, American foulbrood, European foulbrood, Nosema spp., honey bee viruses, and Acarine mite (Acarapis woodi) (Thompson & Wilkins, 2012).

Varroa is present in virtually every colony in Europe. In the absence of treatments, colonies normally die starting with a steep decline in the adult bee population until only a few bees and the queen remains. The mite is also an important transmitter 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 varroa they were generally considered harmless.

The presence of Dwarf Wing Virus, (DWV) is often associated with varroa destructor infestation, and the role of the mite in both the transmission and virulence of the virus has already been experimentally demonstrated. DWV is now considered to be one of the most widespread bee virus in Europe, (Thompson & Wilkins, 2012).

It is also interesting to note that there are stark differences in bee mortality rates between bee keepers in Europe who suffer annual overwintering losses in the range 7-30%, In a recent report by OPERA, the importance of bee keeping practices in managing bee health are emphasized[2]. Furthermore the report highlights the link between declines in bee health and the reduced efficacy of varroa mite treatments over the last 10 years resulting in a devastating shift in the viral landscape, particularly for DWV. In contrast the report notes that incidents of pesticide poisoning have dramatically declined over that period, which is in direct opposition to the trend seen for varroa and DWV.

For its part, thiamethoxam has been used safely on millions of hectares of European crops for over 10 years and there is no incidence of it damaging bee populations. Syngenta is therefore convinced that pesticides in general and thiamethoxam in particular, are not responsible for the reported honeybee losses in Europe.

Unfortunately, some special interest groups have continually tried to implicate this technology in the worrying decline in bee health. They point to unrealistic alarmist studies and ignore overwhelming scientific evidence, referred to above, which shows that loss of habitat and nutrition and the varroa mite (& the diseases it transmits) are the principal causes of poor bee health.

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[1] Efsa media release, 16.1.2013
[2] OPERA Bee health in Europe – Facts and Figures 2013

These special interest groups have never been called to explain why places like Scotland and Switzerland have poor bee health, in spite of the fact that there is very limited use of neonicotinoid seed treatment. Neither can they explain how bee populations thrive in Australia, where neonicotinoids are widely used. Indeed, the Australian government makes it clear that: "*Neonicotinoids are widely used without Australia experiencing Colony Collapse Disorder. While there is occasional evidence of hives being impacted through misuse of pesticides there are few, if any, reports of systemic issues in Australia*"[3].

Yet the review carried out by efsa risks to place the full responsibility for the decline in bee health on neonicotinoid pesticides. Certainly the media reporting of efsa's conclusions have given credence to the spurious argument that the problem can be resolved simply by removing them from the market.

2. The context of the review

Although we acknowledge the best efforts and hard work of efsa in this review, it is impossible to conclude that they have undertaken a thorough investigation of the alleged risks posed by neonicotinoid pesticides to bees or provided any grounds for either a restriction or ban of this technology.

The need to complete the review by the end of 2012, and the changing mandate provided to efsa, eventually meant that the Agency had less than five months to carry out its review for three of the five commercially available neonicotinoid pesticides.

It was also unsuccessful in calling on the resources of Member States to lead the risk assessment process for the individual compounds. For example, Spain, which was the Rapporteur Member State for thiamethoxam, argued that a thorough review of TMX was impossible within the short timeframe and declined to lead this part of the review.

Not surprisingly, efsa has only been able to identify highly theoretical risks which emerge as a consequence of the extremely conservative approach that it perhaps felt compelled to follow. The thorough review of the risks to bee health, originally promised by former Commissioner John Dalli, has certainly not been delivered[4].

3. The methodology for the review

It was obvious from the start that the review of the neonicotinoid pesticides would have to be completed before efsa's new guidance document on the risk assessment for plant protection products and bees had been agreed or implemented.

This meant that efsa had to base its review on the same theoretical and extremely conservative scientific opinion being used to inform the drafting of its new guidance document[5].

This document has proven to be so controversial that efsa received over 1,000 comments delaying its finalization by three months in order to review the input received.

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[3] http://www.apvma.gov.au/news_media/community/2010-11_bees_ccd.php.

[4] Letter to European Food Safety Agency from Commissioner John Dalli, (SANCO/ E3/ MP/sf), 25 April 2012

[5] EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (EFSA Journal 2012; 10(5):2668

It is not an exaggeration to say that if this theoretical and conservative scientific opinion was replicated in efsa's finalized bee risk guidance document, it would be impossible to maintain the registration of any existing insecticides or to register any new ones.

In its review of efsa's report on thiamethoxam, Germany makes clear the limitations of using this scientific opinion which its describes as, "...:*a theory based document [with] limited use for risk assessment purposes*"[6].

Perhaps in recognition of this risk, efsa acknowledges that it would have been preferable to have been able to draw on the final risk assessment guidance document before completing the neonicotinoid review[7].

The intense debate on the merits of the scientific opinion has provided a clear indication that its use in the neonicotinoid review was questionnable. But in light of the Member States' criticism of both the scientific opinion and the draft bee risk guidance document, the fundamental basis which underpinned the review of neonicotinoid pesticides is unlikely to remain valid.

4. Efsa conclusions on the alleged risk posed to bees from thiamethoxam

The report on the alleged risk posed to bees from thiamethoxam identified only two issues which efsa regards as critical areas of concern:

- **High acute risk to bees from dust exposure** on cereals, cotton, oil seed rape (except for lower EU application rates) maize and sunflower (except for lower EU application rates).
- **High acute risk to bees from guttation** in maize.
- **Pollen and nectar were not specifically identified as a critical area of concern** for thiamethoxam, although data gaps were mentioned and these are also addressed in our response below.

The weight of evidence provided by Syngenta and independent authorities, which include studies and field monitoring data, demonstrate that neither of these areas of concern constitute an unacceptable or unmanageable risk to bees from thiamethoxam.

High acute risk to bees from dust exposure

In order to conclude that dust exposure represents a high acute risk to bees, **efsa has used the worst case dust deposition value based on the pneumatic drilling** of seeds treated with thiamethoxam and applied that to all crops. However, in the case of **cereals and oilseed rape, these crops are predominantly drilled mechanically**. If efsa had considered that fact a lower acute risk to bees from dust exposure would have been concluded for these crops.

For maize, the high acute risk to bees from dust exposure is lowered significantly by the consistent application of dust reduction measures during the treatment of maize seed and the use of dust reducing deflector technology in the pneumatic drilling process.

This is proven by our new data from an extensive field testing program conducted in the northern and southern Alsace regions of France (Kriszan, 2012). This field program, which was carried out in

[6] Peer Review Report, 20th December 2012; Member State Coments, page 5
[7] Peer Review Report, 20th December 2012; Member State Comments, page 6

accordance with the EPPO 170 Guideline, investigated the field effects on honeybee colonies placed next to fields drilled with thiamethoxam treated maize (using maximum recommended application rate for maize in the EU).

We did this at 19 treated sites and 3 control sites. At each site, 4 honeybee colonies were monitored for mortality, foraging behavior, colony development and residue analysis before and after the seed drilling period. Over the entire observation period, it was concluded that the exposure of honeybees to dust drift had no effect on mortality, foraging activity, brood development and behavior of honeybees in the thiamethoxam treated fields.

The **dust reduction and risk mitigation measures were not considered by efsa** in their conclusions for thiamethoxam treated maize. Their effectiveness has been demonstrated under real use conditions through monitoring studies conducted by the authorities in both France and Austria.

In France, the regulatory authority found no adverse effects on honeybee colonies between 2008 and 2011[8] and made clear that these measures to reduce exposure to dust had not been considered by efsa in this review[9].

The Austrian authorities said that, *"significant measures have been taken to improve the quality of seed treatment, define strict conditions for the drilling of treated seeds and fully implement deflector technology across the country. The effectiveness of these measures has been demonstrated."*[10]

In 2011, the Rapporteur Member State for thiamethoxam, Spain, concluded "*that the use of deflectors during the drilling process reduces considerably the dispersal of dust containing residues of thiamethoxam".*[11]

The data and information from these Member States provides strong evidence that risk mitigation measures are available and are being used effectively to protect bees from dust during drilling. EFSA did not take any of these practical measures into consideration.

High acute risk to bees from guttation

Efsa has identified a high acute risk to bees from levels of residue of thiamethoxam in guttation droplets from maize crops which occur during the first 3-4 weeks following the emergence of the plant from the ground. However, **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 go into the crop. In practice, this means there would be no risk to bee colonies from guttation.

This is proven by our new data from the extensive field testing program conducted in the northern and southern Alsace regions of France (Kriszan, 2012). This is the same field program which addressed dust drift in maize and is referred to above. The program investigated the effects on honeybee colonies placed next to fields drilled with thiamethoxam treated maize, (again using maximum recommended application rates for maize in the EU). In addition to being exposed to dust

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[8] CIRCA database
[9] ANSES media release, 16 January 2013
[10] Press Statement OVP-Umweltsprecher Hermann Schultes
[11] Annex B, thiamethoxam review by Rapporteur Member State, May 2011

drift, the colonies were also exposed to guttation fluid at a time when the highest residues of TMX would have occurred.

As described in the section above on dust drift, 4 honeybee colonies were monitored across 19 sites of thiamethoxam treated maize and 3 control sites. With respect to guttation, monitoring took place during the early crop emergence. Over the entire observation period, it was concluded that the exposure of honeybees to guttation fluids from maize seeds treated with thiamethoxam had no effect on mortality, foraging activity, brood development and behavior of honeybees in the thiamethoxam treated fields.

These results are consistent with the conclusions from a recently published ICPBR (International Committee on Plant Bee Relationships) guttation investigation (Pistorius et al, 2012) and literature review on neonicotinoid and bees (Thompson et al, 2012).

Finally, the conclusion that guttation poses a high acute risk to bees is based on efsa's mistaken assumption that guttation droplets are 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 local landscape. In addition, guttation droplets predominantly occur during periods of low honeybee flight activity, (e.g. during the early morning). For all these reasons guttation droplets are an inconsequential water source for honeybees as shown in our field trials in the Alsace.

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 concluded that guttation from another crop, e.g. Oilseed Rape, grown with seed treated with neonicotinoid insecticides shows no unacceptable risk to honeybees.

Residues of thiamethoxam in pollen and nectar

In contrast to media reporting, efsa did not find that bees exposed to residues of thiamethoxam in pollen and nectar was an area of critical concern. This is not surprising because the risk to bees from systemic residues of thiamethoxam in pollen and nectar from seed treated crops is low. This has been confirmed by our comprehensive field residue data package submitted to efsa.

In order to confirm this low risk, we investigated the long-term risk to honey bee colonies in the field, including the sensitive overwintering stage, from 4 years consecutive exposure to flowering maize and oilseed rape grown from thiamethoxam treated seeds at rates recommended for insect control.

No treatment related effects were reported on mortality, foraging behavior, colony strength, colony weight, brood development and food storage. Detailed examination of brood development throughout the year demonstrated that colonies exposed to the treated crop were able to successfully overwinter and had a similar health status to the control colonies in the following spring.

This field data better reflects the risk to honey bees in practice than the laboratory studies which use unrealistic exposure conditions. It is worth noting that in the Pesticides Peer Review Meeting 97 (5 – 9 November 2012) where the review of thiamethoxam was first considered by Member States, the following statement 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."

It therefore remains unclear as to why the efsa press release on the publication of the review of the three neonicotinoid pesticides contradicts its own report on thiamethoxam by implying that TMX also posed an acute risk to bees from residues in pollen and nectar.

5. Data Gaps identified by efsa in its report on the alleged risk to bees from thiamethoxam

EFSA has created a set of data gaps which are grossly exaggerated because the review is based on an extremely conservative scientific opinion which several Member States argue is not fit for use in defining data requirements or for risk assessment purposes.

Our comprehensive field data package, which includes state of the art long term field study investigating 4 years' consecutive exposure of bees to nectar and pollen from seed treated with thiamethoxam, was discounted by efsa. This is the same study which was so strongly commended by the Pesticides Peer Review Meeting referenced above. Efsa dismissed it because they argued that the studies were not conducted in accordance with new requirements set out in the heavily criticized scientific opinion.

Once again, Member States like Germany point out that, *"the risk assessment procedures [for field studies]... seem to be highly conservative, in some aspects, even over-conservative"*[12].

In response to a similar observation from Spain, even efsa acknowledged that *"the available field studies were conducted prior to the publication of the scientific opinion and... it is [unsurprising] that the methodology used... did not exactly meet the [new draft] requirements"*[13].

It is worth reiterating the point that if the highly precautionary bee risk requirements were ever applied generally to insecticide field studies, it would take approximately 10 years for industry, Member States and the Commission to complete the backlog of work created. At the end of that process, you would almost certainly find that the new requirements are so precautionary it would be impossible to maintain the registrations of any existing insecticides or register any new ones.

Finally, the presentation of these apparent data gaps in the efsa report infers that the industry has been negligent and ignored risk. This is an outrageous inference when companies like Syngenta have worked closely with Member State authorities to address any new risks identified, fill data gaps and comply with the requests made by authorities.

6. Conclusion

Syngenta strongly believes that EFSA has taken an extremely critical, highly conservative and narrowly informed approach to its evaluation of the risk of thiamethoxam to bees. The science behind the approach used by EFSA is still challenged and remains under debate. EFSA admits that

[12] Peer Review report on thiamethoxam; Member State comments, page 5
[13] Peer Review report on Thiamethoxam; Member States' comments; Page 3

a finalized and agreed guidance document would have been more useful for its evaluation of the neonicotinoid seed treatments[14], and that its conclusions carry a *"high level of uncertainty"*.

In spite of this and because Syngenta is deeply concerned about bee health and is proactive in this area, we can provide data from the new extensive field program referred to in this paper and recent published literature. This addresses the critical areas of concern (dust and guttation) raised by EFSA and fills some of the other data gaps identified. In addition, available field monitoring programs from Member States such as France and Austria have shown that risk mitigation measures are available and can be used effectively at national level to ensure safe use from dust during drilling of thiamethoxam treated seed. Furthermore we have provided monitoring data and independent scientific studies referenced in this response to efsa that confirms the Agency's own conclusion that TMX does not have a high acute risk to bees from pollen and nectar residues.

The efsa review of thiamethoxam has therefore not identified any unacceptable or unmanageable risks to bee health and their report provides no grounds whatsoever for a restriction of this technology.

These facts must also be considered in light of the recent Humboldt Forum for Food & Agriculture study (www.neonicreport.com) which concluded that thiamethoxam along with other neonicotinoid pesticides make an significant socio-economic and environmental contribution to European agriculture and the wider economy[15].

Neonicotinoid seed treatment, in particular, are the most advanced crop protection solutions available for the targeted control of extraordinarily damaging pests. TMX is applied with dose rates typically 10-20 times lower (in some cases 50 times lower) than the best available alternatives and prevent crop losses of up to 40% of the yield. The irony is that should this technology be restricted farmers would produce less using more pesticide.

The loss of crop productivity would be made up by bringing an additional 3m hectares of land into production outside Europe adding an environmental burden of 600m tons of CO_2.

There has never been a stronger case to defend the availability of a technology which benefits everyone and causes no harm to bee populations whose main threats are loss of nutrition and habitat and the impact of diseases and viruses.

Neonicotinoid pesticides may present an easy target for those wanting to "do something for the bee health". After all, pursuing the main causes is much harder and resource intensive. But the evidence against neonicotinoid pesticides is extremely theoretical, based on a controversial scientific opinion described as "highly uncertain" by the main witness, efsa.

Syngenta trusts that the European Commission and EU Member States will fully consider these facts in determining its response to the efsa review of the alleged risks posed by neonicotinoid pesticides to bees.

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[14]Peer Review report on Thiamethoxam; Member States' comments: Page 6;

[15] Humboldt Forum for Food & Agriculture (2013) on the socio-economic and environmental contribution of neonicotinoid seed treatment supported by Copa-Cogeca, European Seeds Association, & the European Crop Protection Association and financed by Bayer Crop Science & Syngenta