MOLNAR Tunde

From: BARLING Jane
Sent: 17 September 2012 09:48
To:
Cc: FONTIER Herman

Subject: RE: Thiamethoxam - request for the submission of studies

Dear

Thank you for your email. We hereby confirm safe receipt of 1 CD containing the additional studies on thiamethoxam.

Thank you for your assistance.

Best regards

Jane Barling

~~~~~~

Jane Barling
Senior Scientific Officer
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1A
43126 Parma
ITALY

Tel : (+39) 0521 036 355
Fax : (+39) 0521 036 0355
Mail to: jane.barling@efsa.europa.eu
Web: www.efsa.europa.eu

From:
Sent: 11 September 2012 16:47
To: FONTIER Herman; BARLING Jane
Cc:

Subject: RE: Thiamethoxam - request for the submission of studies

Dear Herman Fontier and Jane Barling,

The identified missing information is dispatched to your attention today. Since the first study request, some further studies related to bees have been completed and are attached as well.
One of them is dealing with dust drift deposition following drilling of sunflower treated seeds. 3 studies looked after effect on bees during the different stages of thiamethoxam treated maize seeds growing season including specific scrutiny on guttation. Additional studies on effect on bees during maize guttation will be reported by mid October.

In case you need any further information, don't hesitate to contact us.
~~~~~~

Best regards,

From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Freitag, 7. September 2012 16:58
To: C
Cc: ' ; BARLING Jane
Subject: Thiamethoxam - request for the submission of studies

Dear Mr , dear

In April of this year you kindly submitted to EFSA a CD-ROM containing studies on honeybees for thiamethoxam (the previous correspondence below refers).

EFSA has now been requested by the European Commission to perform a risk assessment of neonicotinoids, including thiamethoxam, as regards the risk to bees, and to deliver its conclusions by 31 December 2012. EFSA is currently undertaking the evaluation, and in this context, we have identified further studies (please see attachment) that Syngenta is requested to submit as a matter of urgency. The studies should be submitted to the address given below, marked for the attention of Jane Barling.

Thank you for your cooperation.

Herman Fontier
Head of the Pesticides Unit

European Food Safety Authority
Jane Barling
Via Carlo Magno 1A
43126 Parma
ITALY

Tel : (+39) 0521 036 355
Fax : (+39) 0521 036 0355
Mail to: jane.barling@efsa.europa.eu
Web: www.efsa.europa.eu

From:
Sent: 16 April 2012 12:12
To: BARLING Jane
Cc: ; FONTIER Herman
Subject: RE: CD-ROM studies on honeybees

Dear Miss Barling

We acknowledge your email and the context of our submission of studies on honeybees.

We remain at your disposal for any further comments or questions you may have.

Kind regards

Ph:
Head of Product Stewardship EAME
Syngenta Crop Protection
WRO 1008.7.25
Schwarzwaldallee 215
CH - 4058 Basel
Switzerland
Tel: +
Mobile: -

From: BARLING Jane [mailto:Jane.BARLING@efsa.europa.eu]
Sent: Montag, 16. April 2012 11:58
To: C
Subject: CD-ROM studies on honeybees

Dear

Further to your telephone discussion with Herman Fontier last week, we have now received a CD-ROM of studies on honeybees. Since the CD was not accompanied by a cover letter, we would be grateful if you could kindly confirm the context of this submission by acknowledgement of receipt of this email. Such an acknowledgement would enable us to complete our records with regard to the receipt of mail.

Thank you in advance for your assistance.

Best regards

Jane Barling

~~~~~~

Jane Barling
Senior Scientific Officer
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1A
43126 Parma
ITALY

Tel : (+39) 0521 036 355
Fax : (+39) 0521 036 0355
Mail to: jane.barling@efsa.europa.eu
Web: www.efsa.europa.eu
~~~~~~

syngenta

European Product Registration

Syngenta Crop Protection AG
Schwarzwaldallee 215
WRO 1007.8.xx
P.O. Box
CH-4002 Basel
Switzerland
www.syngenta.com

Tel:
Fax:

Ms Jane Barling
Senior Scientific Officer
Pesticides Unit
European Food Safety Agency
Postal address:
Largo N. Palli 5/A – I-43121 Parma

Re: Thiamethoxam - request for the submission of studies

Dear Ms Barling,

In April EFSA has been requested by the European Commission to perform a risk assessment of neonicotinoids, including thiamethoxam, as regards the risk to bees, and to deliver its conclusions by 31 December 2012. Herman Fontier communicated to us that during its evaluation, EFSA has identified further studies that Syngenta is requested to submit as a matter of urgency.
In the meantime, some further studies related to bees have been completed are attached as well. One of them is dealing with dust drift deposition following drilling of sunflower treated seeds. 3 studies looked after effect on bees during the different stages of thiamethoxam treated maize seeds growing season including specific scrutiny on guttation. Additional studies on effect on bees during maize guttation will be reported by mid October.

Please advise if you require any further information.

Yours faithfully,

Syngenta Crop Protection AG

European Product Registration
SeedCare Team Lead

References
Study reports submitted in attachment are highlighted in red and listed next to the corresponding report.

CAD09(1) – 2285

MOLNAR Tunde

From: MOLNAR Tunde
Sent: 07 Januarv 2013 15:51
To:
Cc: ; FONTIER Herman; MOLNAR Tunde
Subject: RE: Thiamethoxam - EFSA Conclusion on the risk assessment for bees
Attachments: 3067prr.pdf

Categories: Yellow Category

Dear ! ,

Thank you for your confirmation that there is no confidential information in the EFSA Conclusion on thiamethoxam. Your claims for removing confidential information from the Peer Review Report were considered valid and the relevant pages (170 and 171) were blackened accordingly. (Please find attached the amended Peer Review Report as it will be made publicly available).

As regards your comments raised in relation to the sections on concerns, including section 6.2 on critical areas of concerns, please note that these sections reflect EFSA's view and conclusions as identified on the basis of the available information. 'High risk' has been retained in the explanatory note under the definition for "R" in the overview table in section 7 to reflect EFSA's conclusions on the risks identified, and in line with the statements in section 6.2.

We appreciate the additional information and the availability of some new data as detailed in your message, but consider that the conclusion reflects the information that was available to the peer review. As EFSA's remit ended with the finalization of the conclusion, for any follow-up issues in the procedure we kindly refer you to the EU Commission. In the followings, you will be given the opportunity to provide comments on the content of the EFSA conclusion or any additional information, which may be further considered by risk managers (EU Commission and Member States). Any further (or refinement of) risk assessment, if deemed necessary, will be considered by EFSA upon specific request from the EU Commission.

Please note that the EFSA Conclusion is envisaged to be published in the beginning of next week (i.e. week beginning on 14 January 2013).

Thank you for your cooperation.

With kind regards,
Tunde Molnar

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

From:
Sent: 04 January 2013 16:47
To: MOLNAR Tunde; FONTIER Herman
Cc: g
Subject: RE: Thiamethoxam - EFSA Conclusion on the risk assessment for bees

Dear Tunde Molnar,
Dear Herman Fontier,

As already mentioned in your mail EFSA has paid attention not to include any confidential information. We can confirm that we haven't found any confidential information in EFSA Conclusions document. We have very few requests for confidential information removal in Peer Review report on thiamethoxam. Only on pages 170 and 171 of study evaluation notes reference is made to treatment recipes quoting amount of sticker. The relevant parts are blackened on these pages and attached to this mail.

Amendments have been made to EFSA Conclusion following German comments on the wording "high risk identified". Accordingly R* has been removed from conclusion table per crop, but on page 45, in chapter 6.2 Critical area of concern, high risk is still mentioned. We kindly request for EFSA to remove the word high in this chapter to provide a consistent message as the draft guidance on bee risk assessment is not differentiating high risk and risk.

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), maize, and sunflowers (except for uses with the lowest application rate authorised in the EU). A high acute risk was also identified for exposure via guttation fluid for the authorised uses in maize.
The risks identified are marked with an „R" in the overview table in section 7. Risks have been identified where either a 1st tier risk assessment indicated a high risk (not including the screening step assessment for exposure via dust and guttation), or a higher tier study indicated a high risk.

In the EFSA Conclusion document, lack of accuracy in GAP is criticized; but most Member States are not defining sowing rate in registration conditions. As industry we are supportive of a defined seed loading. In case of seed treatment, risk assessment should be based on seed loading only, except for dust off as total quantity of seeds plays a role. Following regulation 2010/21, thiamethoxam seed treatment uses are restricted to professionals (seed companies). Sowing rate of certified seeds is lower compared to farm saved seeds as their cost for farmer is higher and expected germination rate is better. This is particularly valid for hybrid crops such as OSR, sunflower. We can revised our GAP to reflect more the commercial practices if this would be helpful.

In Seed treatment guidance document many references are made to industry generated report on drift of abraded seed treatment dust (Fent, 2011). An updated version of this report has been prepared early 2012 to address some of the questions from German officials. In June 2012, Bayer, BASF and Syngenta disclosed this report to EU Commission and EFSA. We kindly request this report be used in the refinement of dust risk assessment as it covered all industry data generated at that time on dust drift from maize, OSR, cereals and sugar beet.

We have just completed another study on maize using seeds treated with thiamethoxam and monitoring potential effects on bees at drilling and guttation period at the same time period (2010) and in the same region (North and South Alsace) as the 3 reports already reviewed by EFSA. This report covers 19 treatment sites and 3 control sites. We believe this report could provide more background on questions raised during expert meetings related to effects on controls. We would be grateful for advise on how this report could be integrated in the review.

Some observations made by field workers in our cotton guttation study have not been reported but have been noticed by Greek officials when they visited the sites. Thiamethoxam as seed treatment is not providing a very long lasting control of aphids in cotton as the product is unstable in alkaline media such as cotton sap. We have tried for years without success to extend the duration of aphid control in cotton by some formulation work. In our guttation study which was placed next to another product, aphids were back earlier on the thiamethoxam treated plot than on the one treated with competitor product.

Regarding dust drift studies on cotton and sunflower, Peer review open point for EFSA is to check and include information on residues in dust (Heubach-AI). AI concentration in dust from Heubach test has not been reported in the study as it was not a standard for risk assessment at the time the study was initiated. However, these ai concentrations in dust have been measured. For the Sunflower seed lot ST51HA/CR, Heubach test has been performed before shipment of seeds to the sowing site. Heubach and Ai concentration in dust have been measured. Heubach is 4.8 g/ 100 kg seeds, and thiamethoxam concentration in dust was 13.7%.
For the cotton seeds lot SPYRO CM031 used in trial S11-01916-01, Heubach test has been performed before shipment of seeds to the sowing site. Heubach and Ai concentration in dust have been measured. Heubach is 2.19 g/ 100 kg seeds, and thiamethoxam concentration in dust was 9.8%. For the cotton seeds lot PION.6/2011 used in trial S11-01916-02, Heubach test has been performed before shipment of seeds to the sowing site. Heubach and Ai concentration in dust have been measured. Heubach is 3.95 g/ 100 kg seeds, and thiamethoxam concentration in dust was 8.2%.

Best regards

From: MOLNAR Tunde [mailto:Tunde.MOLNAR@efsa.europa.eu]
Sent: Donnerstag, 20. Dezember 2012 09:51
To:
Cc: ; FONTIER Herman; MOLNAR Tunde
Subject: Thiamethoxam - EFSA Conclusion on the risk assessment for bees

Dear Madam,
Dear Sir,

Following request by the European Commission for EFSA to perform a risk assessment of neonicotinoids, including thiamethoxam, as regards the risk to bees, and to deliver its conclusions by 31 December 2012, we are sending you herewith a copy of the EFSA conclusion on the risk assessment for bees for the active substance thiamethoxam, which EFSA has now finalised and forwarded to the EU-Commission.

Please note that this pre-notification of the conclusion is exclusively addressed to the specified recipient, under embargo, for the purpose of consideration of any justified requests for removal of confidential information prior to publication on the EFSA website, and no further disclosure/publication to any third party can take place (please see the attached note on pre-notification under embargo).

EFSA has paid particular attention for the Conclusion not to contain confidential information. However, if you should spot such information, and wish to make any justified requests for removal of confidential information, please inform us by **4 January 2013**, close of business at the latest so that we may consider the matter before placing the complete conclusion on the website.

The Peer Review Report (containing the study evaluation notes, the meeting report and the MS comments on the draft EFSA conclusion) will be sent in a separate email in which you will be given the opportunity to submit justified requests for removal of confidential information prior to its publication on the EFSA website.

We would like to thank you for your support and assistance during the course of the peer review.

With kind regards,

Tunde Molnar

On behalf of Herman Fontier
Head of Pesticides Unit

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

MOLNAR Tunde

From: MOLNAR Tunde
Sent: 20 December 2012 16:02
To:
Cc: MOLNAR Tunde;
Subject: Thiamethoxam - Peer Review Report
Attachments: 3067prr.pdf

Categories: Yellow Category

Dear Madam,
Dear Sir,

Please find enclosed the documents of the Peer Review Report (containing the study evaluation notes, the meeting report and the MS comments on the draft EFSA conclusion) for thiamethoxam. These documents form part of the background documentation to the finalised EFSA Conclusion on the risk assessment for bees and thus will be made publicly available.

Before EFSA discloses this information, we would like to provide you with the opportunity to indicate whether some confidential information should be removed from these documents. If you wish to make any justified requests for removal of confidential information, please inform us by **11 January 2013** at the latest so that they can be considered and evaluated for the public version of these documents.

Please send your justified requests together with the blackened pages, if any, to the EFSA PESTICIDES PEER REVIEW email address (pesticides.peerreview@efsa.europa.eu).

Thank you for your cooperation and assistance.

With kind regards,
Tunde Molnar

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

MOLNAR Tunde

From: MOLNAR Tunde
Sent: 11 January 2013 10:15
To:
Cc: FONTIER Herman; MOLNAR Tunde
Subject: Thiamethoxam - revision to the EFSA Conclusion on the risk assessment for bees
Attachments: Thiamethoxam_Pre-notification under embargo_Applicant.pdf; 3067_rev_clean.pdf; 3067_rev_highlighted.pdf

Categories: Yellow Category

Dear Madam,
Dear Sir,

The EFSA conclusion on the risk assessment for bees for thiamethoxam (EFSA Journal 2013; 11(1):3067) was issued and sent to your attention on 20 December 2012. Following a recent communication with the EU Commission, it has been suggested that some statements in the conclusion should be re-phrased to avoid any possible ambiguities in the interpretation of the final conclusions.
(The changes concern the summary section of the conclusion (page 3) and section 2.1.5 (page 21)).

For your information, please find herewith attached a pre-notification copy of the revised version of the EFSA conclusion on the risk assessment for thiamethoxam (for ease of reference both clean and highlighted versions are attached). Please note that this pre-notification of the Conclusion is exclusively addressed to the specified recipients, under embargo, and no further disclosure/publication to any third party can take place (please see the attached note on pre-notification under embargo).

The revised conclusion, together with the Peer Review Report, is foreseen to be made publicly available on the EFSA website on 16 January 2013.

With kind regards,
Tunde Molnar

On behalf of Herman Fontier
Head of Pesticides Unit

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

MOLNAR Tunde

From: MOLNAR Tunde
Sent: 01 February 2013 17:36
To:
Cc: MOLNAR Tunde
Subject: Thiamethoxam - Updated Peer Review Report
Attachments: 3067prr_rev.pdf

Dear Madam,
Dear Sir,

Please find attached the updated Peer Review Report for thiamethoxam, which has now been updated to include comments from FR, that were transmitted in the context of the written procedure on the draft EFSA Conclusion but were received after finalisation of the EFSA conclusion. These comments, together with EFSA's response to them, have been added to the report: **'03 Comments on the draft EFSA conclusion'**.

No further changes were undertaken.

Please inform us in case you would spot any confidential information on the updated part of the Peer Review Report by **7 February 2013** at the latest. EFSA will then replace the version currently on the website with the updated one.

Thank you for your assistance.

With kind regards,
Tunde Molnar

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

From: MOLNAR Tunde
Sent: 20 December 2012 16:02
To:
Cc: MOLNAR Tunde

Subject: Thiamethoxam - Peer Review Report

Dear Madam,
Dear Sir,

Please find enclosed the documents of the Peer Review Report (containing the study evaluation notes, the meeting report and the MS comments on the draft EFSA conclusion) for thiamethoxam. These documents form part of the background documentation to the finalised EFSA Conclusion on the risk assessment for bees and thus will be made publicly available.

Before EFSA discloses this information, we would like to provide you with the opportunity to indicate whether some confidential information should be removed from these documents. If you wish to make any justified requests for

removal of confidential information, please inform us by **11 January 2013** at the latest so that they can be considered and evaluated for the public version of these documents.

Please send your justified requests together with the blackened pages, if any, to the EFSA PESTICIDES PEER REVIEW email address (pesticides.peerreview@efsa.europa.eu).

Thank you for your cooperation and assistance.

With kind regards,
Tunde Molnar

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

MOLNAR Tunde

From: MOLNAR Tunde
Sent: 12 March 2013 10:34
To:
Cc: FONTIER Herman

Subject: Thiamethoxam - amendment to the EFSA Conclusion on the risk assessment for bees
Attachments: 3067_rev2_highlighted.pdf; 3067_rev2_clean.pdf; Thiamethoxam (revision)_Pre-notification under embargo_Applicant.pdf

Categories: Red Category

Dear Madam,
Dear Sir,

The EFSA Conclusion on the risk assessment for bees for thiamethoxam was published on 16 January 2013 (EFSA Journal 2013; 11(1):3067).

Following corrections reported recently by Sweden and Greece in their GAP data in relation to some of the authorised uses as a seed treatment on sunflower, oilseed rape and sugar beet, the Conclusion on thiamethoxam has been revised to take into account the appropriate maximum application rates in the risk assessment for these uses, where relevant. As a consequence, for the use of treated sunflower seeds in Greece the outcome of the acute risk assessment from dust exposure has been changed from "risk identified" to an "issue that could not be finalised". The outcome of the risk assessment for the other uses on sunflowers as well as for the uses of treated oilseed rape and sugar beet seeds remained unchanged.

For your information, please find herewith attached a pre-notification copy of the revised version of the EFSA Conclusion on the risk assessment for thiamethoxam (for ease of reference both clean and highlighted versions are attached). Please note that this pre-notification of the Conclusion is exclusively addressed to the specified recipients, under embargo, and no further disclosure/publication to any third party can take place (please see the attached note on pre-notification under embargo).

Please note that since the changes are straightforward and concern only recalculations using the correct application rate data, a sanitisation exercise is not foreseen at this stage.

Please note that the revised Conclusion will be made publicly available on the EFSA website, as a replacement of the currently available Conclusion, on **14 March 2013.**

Thank you for your assistance.

With kind regards,
Tunde Molnar

On behalf of Herman Fontier
Head of Pesticides Unit

Ms Tunde Molnar
Scientific Staff - Coordination
Pesticides Unit

European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma, Italy
Tel: (+39) 0521 036 514
Fax: (+39) 0521 036 0514
Email: tunde.molnar@efsa.europa.eu
http://www.efsa.europa.eu

FONTIER Herman

From:
Sent: 29 November 2012 17:45
To: FONTIER Herman
Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear Herman,

Thank you very much for your response to my earlier question.

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:
Mobile

-----Original Message-----
From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Mittwoch, 28. November 2012 18:11
To:
Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear

EFSA will give you an opportunity to identify CBI prior to publication. As mentioned in one of my earlier mails, I assume the Commission will consult the applicants on the Conclusions, as they always do (that is, after adoption by EFSA). But it's of course up to COM to decide on that.

Kind regards,

Herman

-----Original Message-----
From:
Sent: 28 November 2012 18:01
To: FONTIER Herman
Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear Herman,

is there an option for me to talk to you on the phone over the coming days to clarify the open question with you?

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:
Mobile:

-----Original Message-----
From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Mittwoch, 21. November 2012 15:47
To:
Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear

I'm not in the office this week. Please permit me to come back to you next week.

Kind regards,

Herman

From:
Sent: Wednesday, November 21, 2012 2:06 PM
To: FONTIER Herman
Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear Herman,

Forgive me for asking a process question on the ongoing risk assessment on neonicotinoids, but it will be extremely helpful for us to understand the following point:

At completion of the risk assessment on neonicotinoids due end of December 2012, will applicants, e.g. Syngenta, receive the final draft for a check on proprietary information (as it is the case with active substance assessments) prior to publication by EFSA or will the document be published immediately after completion and it will be up to the Commission to allow time for comments by applicants?

Thank you very much for your help on this procedural aspect!

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:
Mobile: +

From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Dienstag, 6. November 2012 09:44
To:

Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear

This is not foreseen. I assume the Commission will consult the applicants on the Conclusions, as they always do.

Kind regards,

Herman

From:

Sent: 06 November 2012 07:50
To: FONTIER Herman
Subject: FW: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear Herman,

The pesticide peer review meeting on 5th to 9th November 2012 will discuss draft EFSA conclusions on the risk to bees for the neonicotinoid active substances thiamethoxam, clothianidin and imidacloprid. Thiamethoxam is Syngenta's substance. Does this qualify the company to receive a copy of the draft document?

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:
Mobile:

From: FONTIER Herman
[mailto:Herman.FONTIER@efsa.europa.eu]<mailto:[mailto:Herman.FONTIER@efsa.europa.eu]>
Sent: Montag, 29. Oktober 2012 17:39
To:
Subject: Re: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear

Yes, we are on schedule for meeting that deadline.

Kind regards,

Herman

From:

Sent: Monday, October 29, 2012 05:17 PM
To: FONTIER Herman
Subject: RE: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear Herman,

thank you very much for this clarification, your rapid response to our question is much appreciated. I understand from your reply that EFSA will meet the end of year deadline for the bee risk assessment on thiamethoxam, clothianidin and imidacloprid.

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:
Mobile:

From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Montag, 29. Oktober 2012 12:01
To:
Subject: Re: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear

In its mandate to EFSA, the Commission has requested EFSA to consider for the neonicotinoids the Scientific Opinion on the science behind the risk assessment for pesticides/bees (which is the basis for the guidance document). The Commission knew the guidance would not be ready in time in order to consider it for the neonicotinoid Conclusions, which need to be finalised by the end of the year. Therefore the reference to the Scientific Opinion.

Kind regards,

Herman

From:

Sent: Monday, October 29, 2012 10:56 AM
To: FONTIER Herman
Subject: FW: Draft conclusion on the risk to bees of neonicotinoid active substances

Dear Herman,

Syngenta would appreciate your input on a procedural matter with regard to a DG SANCO mandate for EFSA to assess bee risks of three neonicotinoid active substances:

Through ECPA Syngenta received the EFSA timetable for round 28, pesticide peer review expert's meetings and teleconferences October-November 2012. Based on this document the pesticide peer review meeting on 5th to 9th November 2012 will discuss draft EFSA conclusions on the risk to bees for the neonicotinoid active substances thiamethoxam, clothianidin and imidacloprid. This date seems to be out of synch with the process to complete guidance on bee risk assessment. To our knowledge this guidance is in public consultation until 12th November. In the absence of such guidance Syngenta wonders what the basis will be for EFSA to assess bee safety of the three active ingredients. An assessment not considering the bee guidance document currently in preparation could be seen to be incomplete at the moment it is being published.

Your help is much appreciated to clarify this procedural point for us.

Best regards,

(
Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:
Mobile:

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

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This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

FONTIER Herman

From:
Sent: 16 January 2013 10:52
To: FONTIER Herman
Subject: RE: A question to an EFSA press release

Dear Herman,

thank you for your response.

Best regards,

From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Mittwoch, 16. Januar 2013 07:21
To:
Subject: Re: A question to an EFSA press release

Dear

I'm attending a meeting in ECHA, and I don't have any neonic documents with me. I'm aware of the letter sent yesterday by Syngenta, and my understanding is that it will be discussed in EFSA this morning.

Kind regards,

Herman

From:
Sent: Wednesday, January 16, 2013 06:44 AM
To: FONTIER Herman
Subject: A question to an EFSA press release

Dear Herman,

the EFSA press release on neonicotinoids has be brought to our attention and I have a question on this document. Would it be possible to briefly talk on the phone this morning to clarify this open point?

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

FONTIER Herman

From:
Sent: 12 February 2013 16:24
To:
Cc: FONTIER Herman
Subject: FW: What do you think about this letter to
Attachments: Comments on EFSA review conclusions (4).pdf

Dear

An in-depth review of the EFSA conclusion on thiamethoxam, issued by EFSA on 16th January 2013, has revealed a major error in one of the assumptions upon which the agency based its risk assessment. For oilseed rape and sunflower the assumed sowing rates were unrealistically high, a fact that was highlighted by Syngenta in a letter to DG SANCO on 30th January 2013. In the meantime other sources, including participants of the Advisory Group on the Food Chain, Animal and Plant Health, have provided similar input to DG SANCO.

The attached response of Syngenta to the EFSA Conclusions reviews the calculation of key parameters in risk assessment. Using realistic sowing rates as a basis for these calculations results in the conclusion of a low risk from dust of oilseed rape and sunflower. It also provides further and highly relevant elements underpinning the fact that thiamethoxam residues in pollen and nectar of oilseed rape do not represent a relevant risk for the survival and overwintering success of bee populations.

This review of the EFSA conclusions for thiamethoxam undermines the European Commission's proposed approach which attempts to draw the same negative conclusion for all three compounds reviewed and questions the use of bee attractiveness as the parameter driving regulatory decisions on thiamethoxam and other neonicotinoids. Syngenta request that this decision making process is stopped and not resumed before the conclusions by EFSA have been reviewed in the light of these new facts.

Best regards,

Hea

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone

Response to the EFSA conclusions on thiamethoxam identifying risks from dust as well as residues in pollen and nectar

At the recent meeting of the Advisory Group on the Food Chain, Animal and Plant Health, DG SANCO was made aware by several participants of unrealistic assumptions on sowing rates the EFSA used in their assessment on Neonicotinoids. These comments underpin the argumentation in a letter to the Commission sent by Syngenta on 30th January 2013.

Sowing rates

In the conclusions on thiamethoxam issued by the EFSA on 16th January 2013 the Agency used sowing rates for oilseed rape and sunflower, which fail to reflect current agricultural practices. The Agency missed to consider the following facts:

1. The seeding rates approved by MS consider loss of crop emergence due to diseases and pests. However, seed treatment products, in particular thiamethoxam, reduce such losses to a large degree. Emergence of crops from treated seeds is significantly higher compared to untreated seeds. Therefore sowing rates for treated seeds are significantly lower.
2. Directive 2010/21 restricts the use of thiamethoxam seed treatments to professional users. Such users are seed producing companies and their thiamethoxam treated seeds are certified to provide a defined germination rate. Because of the higher price of such certified seeds farmers use lowest possible seeding rates.

The realistic maximum seeding rates for oilseed rape is 4kg/ha (EFSA used 10kg/ha) and for sunflower 5kg/ha (EFSA used 20kg/ha). The following tables translate these realistic maximum seeding rates into Good Agricultural Practice (GAP) for the seed treatments.

Crop	Product Name	Application rate per treatment			
		g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate (average)
Oilseed rape	Cruiser OSR	8.4	16.8	420 g/100 kg seeds	Hybrid winter oilseed rape 2 - 4 (2.5) kg seed/ha Conventional winter oilseed rape 2 - 4 (3.5) kg seed/ha Spring oilseed rape 2 - 5 kg seed/ha
Sunflower	Cruiser	16.4	21.9	437.5 g/100 kg seed	40000-80000 (65000) seeds/ha TGW 50-100 4 - 5 kg seed/ha

Recalculations of Tier 1 HQ values for **oilseed rape** presented in Table 4 on page 12 of the EFSA conclusions are (corrected numbers in red):

Crop	Parameter	Lowest 'maximum application rate' authorised in the EU	Highest 'maximum application rate' authorised in the EU
Oilseed rape	Application rate (g a.s./ha)	8 (8.4)	42 (16.8)
	% deposition (adjacent vegetation)	2.7	2.7
	Predicted off-field deposition rate (g/ha)	0.216 (0.227)	1.134 (0.454)
	Acute oral HQ[2]	23.1 (24.3)	121.2 (48.5)
	Acute contact HQ[3]	9.0 (9.5)	47.3 (18.9)

[2] Calculated using an acute oral LD_{50} of 0.00936 µg a.s./bee for dust from formulation A9700B (see table 1)
[3] Calculated using an acute contact LD_{50} of 0.024 µg a.s./bee from a standard laboratory study (see table 1)

Calculations in the table above demonstrate beyond doubt that on a theoretical basis the risk from dust of thiamethoxam treated oilseed rape is low. The result of this theoretical approach is confirmed by practical experience with thiamethoxam as a seed treatment for oilseed rape in Germany. In the peer review process German authorities stressed the fact that "for about 15 years, and up to today, there has been not a single incident which could be possibly related to dust drift during sowing of winter oilseed rape." It is hard to understand how such compelling evidence for the safe use of the substance was ignored by EFSA.

Recalculations of Tier 2 HQ values for **sunflower** presented in Table 6 on page 16 of the EFSA provides the following results (corrected numbers in red):

Application rate	16.4 g a.s./ha		63 (21.9)g a.s./ha	
	Without deflector	With deflector	Without deflector	With deflector
% of applied rate in Petri dish	-	0.106	-	0.106
Predicted off-field deposition rate (g/ha)	-	0.02	-	0.07 (0.0232)
Predicted off-field deposition rate with factor of 10[1] (g/ha)		0.17		0.67 (0.232)
Acute oral HQ[2]	-	18.6	-	71.3 (24.8)
Acute contact HQ[3]	-	7.2	-	27.8 (9.67)

[1] A factor of 10 was applied to the exposure estimate to account for extrapolation of residues on 2-D Petri dishes to 3-D plant structures taking account of interception of the plants (EFSA 2012a).
[2] Calculated using an acute oral LD_{50} of 0.00936 µg a.s./bee for dust from formulation A9700B (see table 1)
[3] Calculated using an acute contact LD_{50} of 0.024 µg a.s./bee from a standard laboratory study (see table 1)

These results show that for realistic sowing rates the relevant HQ values are well below 50 which clearly indicates a low risk for the entire range of sowing rates and not just for the low rates as EFSA concluded. In addition extrapolation factor for horizontal to vertical deposition of

dust was extremely conservative. Recent publication[1] from German officials indicate a >50% reduction of the extrapolation factor to apply for deposition on vegetation.

Residues in pollen and nectar

The Syngenta field studies on oilseed rape have clearly demonstrated the absence of a risk to bee colonies from exposure to pollen and nectar. These studies were considered by experts involved in the peer review process as "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". Not only did EFSA disqualify these studies, the Agency also ignored the fact that they cover the parent substance as well as its metabolite clothianidin. The results of the Syngenta studies are fully supported by a German bee monitoring project, which started in 2004 and is on-going to this date. Published results on overwintering losses (Genersch et al 2010[2]) found several factors to be significantly related to the observed losses. Among these relevant factors were Varroa infestation, infection with deformed wing virus and acute bee paralysis virus in autumn. Despite careful evaluation this same research was unable to demonstrate a correlation between overwintering losses and exposure of bees to oilseed rape grown from thiamethoxam treated seeds.

Conclusions

1. Risks from dust identified by EFSA in its conclusion on thiamethoxam for oilseed rape and sunflower are based on unrealistic sowing rate assumption. Risk calculations using the sowing rates that apply for certified seeds as they are marketed by professional seed treatment facilities in line with Commission Directive 2010/21/EC demonstrate a low risk of exposure to dust of honey bees. Such a low risk does in no way justify any regulatory actions to restrict the use of thiamethoxam on these crops as they are now proposed by the Commission.
2. The EFSA conclusions identified a risk for bees from exposure to pollen and nectar of oilseed rape. Syngenta field studies in oilseed rape over four consecutive years covering both thiamethoxam and its metabolite clothianidin, demonstrated no indications for a risk to bee colony survival. These Syngenta studies are fully supported by comprehensive research in Germany, including bee health monitoring and an incident investigation scheme. This research demonstrated absence of adverse side effects on bees, including parameters like mortality, orientation, colony and brood development.
3. The above conclusions seriously question the Commission approach to use bee attractiveness of crops as the parameter to drives regulatory action. The fact that for two such crops safe use is demonstrated requires the Commission to halt the ongoing process on neonocotinoids and review the approach in this case.

Basel, 12th February 2013

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[1] U. Heimbach, M. Stähler, K. Schwabe, D. Schenke, J. Pistorius, P.-Th. Georgiadis, 2012 Dust drift emission during sowing, Presentation at Diabrotica conference, Berlin Nov 2012

[2] Genersch et al, 2010: the German bee monitoring project: a long term study to understand periodically high winter losses of honey bee colonies; Apidologie 41 (2010), 332-352.

FONTIER Herman

From:
Sent: 14 February 2013 22:17
To: FONTIER Herman
Subject: FW: EFSA Conslusions on thiamethoxam

Dear Herman,

Syngenta is fully aware of the sowing rates reported by MS as mentioned in your e-mail. In our view it is neither reasonable nor credible under any scientific aspect to be guided by such hypothetical exposure scenarios.

The reason for our view is the following: Directive 2010/21/EC restricts the use of neonicotinoid seed treatments to professional seed treatment facilities. This means the use of the substances is possible only for companies which produce high quality certified seeds. Such high value seeds are expensive, and, as a consequence, no commercially minded market participant would use more than the absolute minimum amount of seeds to achieve a successful crop.

The fact that EFSA's sowing rates were excessive was also highlighted by France during the peer review process, and participants in the Advisory Group of the Food Chain, Animal and Plant Health made similar comments.

As a science based company we struggle to understand why an organization like the EFSA is so completely focused on highlighting hypothetical risks when Art 23 (f) of Regulation(EC) No 178/2002 requests the Agency "to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the field of its mission."

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:

From: FONTIER Herman [mailto:Herman.FONTIER@efsa.europa.eu]
Sent: Mittwoch, 13. Februar 2013 17:22
To:
Cc: ; ARENA Francesca; ; SZENTES Csaba; AUTERI Domenica;
Subject: RE: EFSA Conslusions on thiamethoxam

Dear

For the sowing rates, EFSA used the GAP tables provided by the Member States. Data were included in an excel spreadsheet, reporting for each use the range (min and the max). The risk assessments performed by EFSA used the highest and lowest 'maximum application rate' which were specified in the GAP tables. Therefore, the risk assessments covered the range of the authorised uses in the EU. The reason for using the lowest 'maximum application rate' (as opposed to the absolute minimum) was to ensure that the risk assessment encompassed the likely exposure for the authorised uses.

Specifically for the thiamethoxam assessment for sunflower, the highest 'maximum application rate' of 63 g a.s./ha with a sowing rate of 22 kg seeds/ha, was related to the authorised use in Greece (information provided by Greece). For oilseed rape the highest maximum application rate was reported by Sweden (42 g a.s./ha) and the GAP table indicated a sowing rate of 10 kg seeds/ha.

Assuming that the information provided by the Member States is correct, there is no error in the EFSA Conclusions and a correction is thus not needed.

Kind regards,

Herman

From:
Sent: 12 February 2013 18:00
To: FONTIER Herman
Subject: EFSA Conslusions on thiamethoxam

Dear Herman,

An in-depth review of the EFSA conclusion on thiamethoxam, issued by EFSA on 16th January 2013, has revealed a major error in one of the assumptions upon which the agency based its risk assessment. For oilseed rape and sunflower the assumed sowing rates were unrealistically high, a fact that was highlighted by Syngenta in a letter to DG SANCO on 30th January 2013. In the meantime other sources, including participants of the Advisory Group on the Food Chain, Animal and Plant Health, have provided similar input to DG SANCO.

The attached response of Syngenta to the EFSA Conclusions reviews the calculation of key parameters in risk assessment. Using realistic sowing rates as a basis for these calculations results in the conclusion of a low risk from dust of oilseed rape and sunflower. It also provides further and highly relevant elements underpinning the fact that thiamethoxam residues in pollen and nectar of oilseed rape do not represent a relevant risk for the survival and overwintering success of bee populations.

Syngenta believes the error made by EFSA in the assumptions on sowing rates of thiamethoxam treated oilseed rape and sunflower seeds fully justifies a correction to the Conclusions of EFSA. We appreciate hearing from you again on this matter.

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:

FONTIER Herman

From:
Sent: 19 March 2013 18:06
To: FONTIER Herman
Cc:
Subject: Protocol for monitoring studies

Dear Herman,

in order to close data gaps identified by EFSA in their assessment of the thiamethoxam dossier, Syngenta is considering bee monitoring studies, potentially on a large scale, to cover the use of the substance in more than one Member States. The challenge the company is facing with such a project is the lack of an approved study protocol. The bee risk assessment guidance is still under development and the protocols used by Syngenta and others stakeholders in previous studies have been rejected by EFSA.

I am contacting you today to get advice on a protocol for a bee monitoring study to accompany the use of thiamethoxam in various Member States. Given the high cost of such a study, the company wants to maximize the chances for the study to be accepted by authorities reviewing it. Considering the fast approaching drilling season 2013 for maize, I would appreciate a response at your earliest convenience.

Thank you very much for your help.

Best regards,

Syngenta Crop Protection AG
Schwarzwaldallee 215
P.O- Box
4002 Basel
Switzerland
Phone:

MOLNAR Tunde

From: [redacted]
Sent: 12 March 2013 15:23
To: FONTIER Herman; BARLING Jane; GESLAIN-LANEELLE Catherine
Cc: MOLNAR Tunde
Subject: EFSA peer review of the pesticide risk assessment for bees for the active substances imidacloprid and clothianidin
Attachments: BCS Letter to EFSA.pdf; 02-21-13_EFSA_Review.pdf

Dear Ms. Barling, Ms. Geslain-Laneelle and Mr. Fontier,

Bayer CropScience has in detail reviewed the recent risk evaluation conducted by EFSA for two of our substances imidacloprid and clothianidin regarding pollinator species. In addition to our own analysis and in order to be able to critically reflect our conclusions of the EFSA report, we have commissioned to an independent panel of bee scientists a critical review of the EFSA risk assessment approach and have asked them to come up with an own unbiased opinion. This panel has recently completed their review, and we now want to take the opportunity to share with you their conclusions. Please, find a copy of the report and a summary of the key conclusions of this expert panel attached to this e-mail. The attached letter and a hardcopy of the expert panel report has been sent today by separate mail to Mrs. Molnar.

Please, do not hesitate to contact me in case of any further questions regarding these attachments. I will be glad to answer your questions and provide further information to you at any time.

Best regards,

Bayer CropScience

Science For A Better Life

Bayer CropScience Aktiengesellschaft
BCS AG-R&D-D-EnSa
Monheim. 6650
Tel
Fax:
E-mail:
Web: http://www.bayercropscience.com

Please visit our anniversary website:
Bayer: 150 Years Science For A Better Life

Bayer CropScience

Tunde Molnar
Scientific Staff -
Coordination,Pesticides Unit
European Food Safety Authority
Via Carlo Magno 1/A
43126 Parma
Italy

Subject: EFSA peer review of the pesticide risk assessment for bees for the active substances imidacloprid and clothianidin

2013-03-12

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Vorsitzender des Aufsichtsrats:
Werner Baumann

Sitz der Gesellschaft:
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Eintragung:
Amtsgericht Düsseldorf

Dear Ms. Molnar,

Bayer CropScience has in detail reviewed the recent risk evaluation conducted by EFSA for two of our substances imidacloprid and clothianidin. In addition to our own analysis and in order to be able to critically reflect our conclusions of the EFSA report, we have commissioned to an independent panel of bee scientists a critical review of the EFSA risk assessment approach and have asked them to come up with an own unbiased opinion. This panel has recently completed their review, and we now want to take the opportunity to share with you their conclusions. Please find the E^{x}ponent® report attached. Funding was provided by Bayer CropScience who, however, had no review or oversight of the report's content. As declared by the authors, the comments are solely those of the reviewers.

The main findings of the E^{x}ponent® report are:

- Based on a comprehensive review of existing analyses on causality of bee declines at a global scale, E^{x}ponent® concluded that the weight of evidence from the U.S., Europe, and Canada indicates that overwintering losses are caused primarily by inadequate fall hive maintenance, resulting in weak hives going into winter. The epidemiological evidence from Europe does not show any correlation to pesticides, and indicates the clear presence of causal factors other than pesticides.
- The primary shortcoming of the EFSA assessment is seen in its complete reliance on worst-case exposure scenarios, some of which have been observed in the laboratory but not in the field. "The EFSA assessment concatenates so many unlikely worst-case scenarios with so many unknown elements, that the

probability of bees in natural situations actually achieving the calculated risk level is very low." E^ponent® finally concluded that the EFSA risk assessments use unrealistic exposure values, make inappropriate comparisons to toxicity threshold levels, fail to consider critical bee behaviors, and inappropriately discount monitoring and field studies. Therefore, the EFSA evaluation amounts to only a Tier I risk assessment that overstates the risks to honey bees.

- The panel concludes that the approach used by EFSA should be considered an initial screen (i.e., highly worst case), and not predictive of risk to honeybees under field conditions. A more appropriate conclusion at this time is that data are lacking to complete the assessment for some exposure routes, and that further analysis (e.g., probabilistic or "reasonable case" assessments) should be conducted.

To conclude, we strongly believe that a scientifically sound risk assessment has to be based upon data generated under relevant use conditions. Rather than discounting all available information from studies conducted under agronomically relevant use conditions, a weight-of-evidence approach would have been an appropriate tool to evaluate the risk under field conditions. Numerous studies conducted under relevant field conditions in different member states consistently demonstrated that honeybees are not harmed by neonicotinoid seed treatment uses, if applied properly. These findings are further substantiated by the experience of Bayer CropScience as the major breeder of spring oil seed rape (canola) seeds in Canada. For production of Canola seed pollination service is essential and although seeds of the parental lines had always been treated with neonicotinoids to ensure crop health no incident or bee colony impact has ever been recorded over more than a decade of use.

Bayer CropScience is fully committed to work with all competent authorities and stakeholders to continue to validate appropriate methodologies and to improve and refine risk assessment for honeybees.

Best regards
Bayer CropScience AG

ppa.

Cc. H. Fontier, J. Barling, G. Laneelle
– via email only