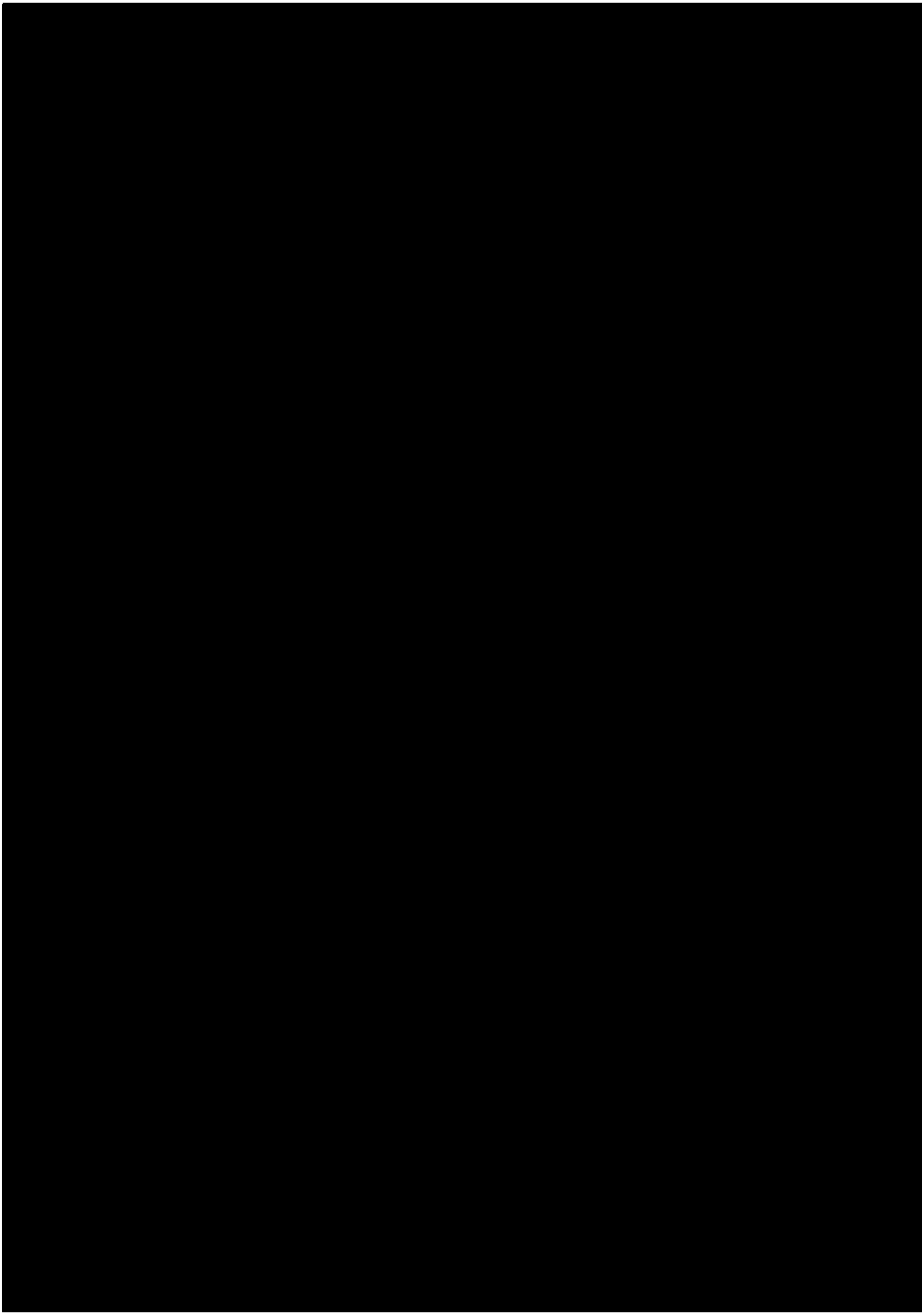

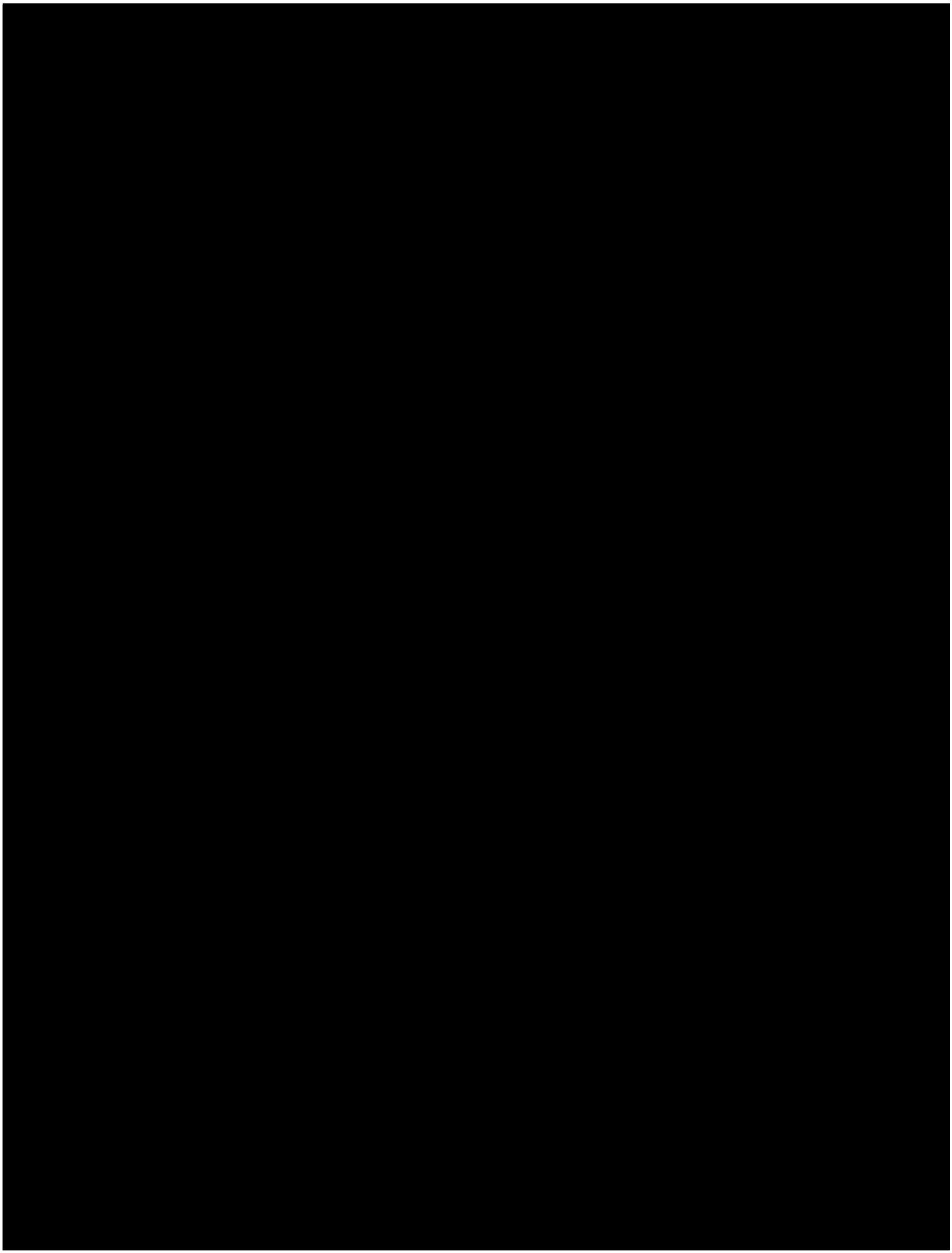

[redacted]

From: [redacted]
Sent: 10 July 2012 10:06
To: PS/Jim Paice (Secretariat)
Cc: [redacted]
Subject: Syngenta - Cruiser OSR - letter + copy of formal response to French govt

Dear Minister,

As you will be aware the French government has now moved formally to withdraw our product Cruiser OSR in France. We remain strongly opposed to this decision, question its legality, and believe that it fails to take into account the scientific evidence that supports the continued registration and use of our product.

Ahead of the next Standing Committee on the food chain and animal health (SCFCAH) at which the French will outline to Member States their reasons for withdrawal please find attached the following documents:

- A letter from [redacted] providing an update on the decision taken by the French government to ban Cruiser OSR in France
- Syngenta's formal response to the French government after their announcement of the intention to ban Cruiser OSR in June, which provides a detailed technical critique of the rationale being used to justify the decision

Regards,

[redacted]
Syngenta
Jealott's Hill International Research Centre
Bracknell, Berks RG42 6EY
[redacted]

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Registered with acknowledgement of receipt

DIRECTORATE-GENERAL FOR FOOD
Mr Patrick DEHAUMONT
Director-General ,
251, rue de Vaugirard

75732 Paris Cedex 15

Guyancourt, 15 June 2012

Subject: Observations in reply to the notification of the intention to withdraw the authorization for commercial sale of the product Cruiser OSR®, Sale Permit AMM No. 21000180

Dear Director-General,

By registered letter dated 31 May 2012 received by us on 4 June, you notified us of your intention to withdraw the authorization for the commercial sale (AMM) of the product Cruiser® OSR, AMM No. 2100180.

That intention follows your interpretation of the new information brought to your attention in the opinion of the National Agency for Food Health & Safety, the Environment and Labor ("ANSES") dated 31 May 2012 "*relating to a request for scientific and technical support in the context of the publication of the article entitled "A common pesticide decreases foraging success and survival in honey bees.*" That opinion (the Opinion) was published on 1 June last.

To begin with, we wish to state the reasons for which we find it absolutely impossible to understand the intention of withdrawal because:

(i) It cannot in any way be linked to the conclusions of the Opinion delivered on the occasion of the publication of a non-validated experiment which has been the subject of numerous criticisms in the Opinion itself;

(ii) Nor can it be based on the opinion of the European Food Safety Authority (EFSA) published on 1 June 2012.

We will go on to develop the arguments in response to what seem to us to be the explanations for your action.

1. **The intention of withdrawal is incomprehensible**

a. The opinion of ANSES

It is imperative to recall the purpose of the referral to ANSES and the very clear replies which have been given.

This agency was asked:

- *to indicate whether the dose administered in the experiment to which the report in the article relates corresponds to situations which are representative of the exposure of bees in the natural environment, and*
- *whether this work is liable to call into question the conclusions of the previous risk assessments performed on the active substance thiamethoxam and the different products containing that substance.*

ANSES reached the following conclusions (in the extracts set out below and in the following passages – our underlining):

- On the first point:
  "*The interpretation by the authors to the effect that the thiamethoxam dose of 1.34 ng/bee may be commonly encountered in the field is therefore regarded as not being verified by the available observations.*"

- On the 2nd point:
  "In the present state of knowledge, the results presented in the article by Henry et al. 2012 ***are not deemed to call into question the conclusions of the risk assessment conducted within the framework of the application file for authorization of the commercial sale of the Cruiser OSR preparation according to the current regulatory criteria***, but do highlight certain limits of the methodologies used within this framework in respect of their sensitivity. **The properties of toxicity for bees taken into account for the approval of thiamethoxam pursuant to Regulation (EC) No. 1107/2009 14 and indicated on page 8 of this opinion are not altered by the outcomes of this study.**"

ANSES therefore gave a positive and very direct reply to the two questions which were put to it and it did so with no ambiguity.

It is all the more surprising that an intention of withdrawal could be based on the preliminary results of a single experiment, **which has not been validated at the national and international levels** and is marred by a significant number of experimental shortcomings noted both by ANSES and by EFSA. It seems likely that, in view of the many uncertainties, the repetition of this same experiment, with or without a correction of its principal defects or its transposition into the field (with natural foraging on oilseed rape treated with Cruiser OSR) might give very different results.

b. The opinion of EFSA

The two following questions were put to EFSA by the European Commission:

(1) *Are the doses used in the studies referred to in the new scientific articles comparable to the actual doses to which bees are exposed, based on the supported uses at EU level and on the authorisations granted by Member States?*
(2) *Could the new results be applied also to other neonicotinoids used for seed treatment, and in particular to clothianidin?*

EFSA replied to the 1st question in its opinion published on 1 June 2012: "*Overall, before drawing definite conclusions on the behavioural effects regarding sub-lethal exposure of foragers exposed to actual doses of neonicotinoids and the consequences to the colony it would be necessary to repeat the experiments performed in the studies with other exposure levels or in other situations.*" That is repeated in substance in its press release which was also published on 1 June last: "*Nevertheless, before drawing definitive conclusions on the effects of neonicotinoids on the behaviour foraging bees and colonies of bees on the basis of the effective doses, it would be necessary to repeat the experiments performed in the studies by taking account of others levels of exposure and other situations.*"

ANSES and EFSA therefore finally make the same recommendation: this experiment should be repeated, in particular with adjustments to the experimental protocol to move closer to realistic conditions. This proves implicitly that the methodology used by Henry et al. does not enable conclusions to be drawn in respect of the risk incurred by the bee colonies under the conditions prevailing in farming practice. This also illustrates the fact that the protocol used has not, as things stand at present, been validated at national and international level with a view to its integration into the risk assessment models.

2. Reasons for the intention to withdraw the permit

On reading your aforementioned letter of 4 June 2012, the notification of the intention to withdraw the permit for the commercial sale of the product Cruiser OSR seems in the end to be based on just two points which differ from the questions put initially to ANSES:

- *"ANSES takes the view that the results show the effect of a sub-lethal dose of thiamethoxam on the return of foraging bees to the hive."*
- *"Although the data submitted or the field analyses performed in 2012 show that the exposure of the bees to thiamethoxam through the residues of oilseed rape nectar is less than the dose taken into account in the experimentation (by Henry), exposure to doses of this level cannot be totally ruled out."*

We will therefore endeavor primarily to show:

- That the reference to sub-lethal effects in the ANSES opinion is no more than a simple observation in eco-toxicological terms enabling the experimental foundations of the study by Henry et al. to be presented without, however,

validating the pertinence of the results of that experiment. The presence of sub-lethal effects of thiamethoxam is not in itself a new observation.

- That working with the available data, the artificial and excessive exposure to which the experiment performed by Henry et al. exposed the bees cannot be observed under natural conditions.

a. Sub-lethal effects of thiamethoxam

A sub-lethal effect is by definition an adverse effect on the behavior or physiology of an organism which is observed with a dose that does not result in the death of the individual concerned.

In the case covered by this particular study, the dose of 1.34 ng of thiamethoxam/bee administered by the authors represents nearly one-third of the LD50 of 5 ng/bee. Now a LD50 is a dose at which mortality is observed; this is in fact a dose with which 50% of the individuals die following such contamination. Thus, EFSA in its scientific position published previously on bees[1] indicates the level at which the sub-lethal doses must be assessed: "*Sub-lethal doses can be defined as a fraction of the LD50 (the amount of a solid or liquid material that it takes to kill 50% of test animals in one dose) and are often an order of magnitude below such lethal doses (below LD50/10).*" In other words the sub-lethal dose would be in the order of 0.5 ng thiamethoxam per bee.

The study by Henry et al. is therefore positioned at exposure levels that are much closer to a lethal effect, especially as the LD50s are traditionally determined for bees placed in small cages and which therefore expend very little energy; they are confined and to all intents and purposes do not fly. But that is not the case in the study by Henry et al. in which the foraging bees first receive a dose relatively close to LD50 and are then released at a distance of 1 km from the hive (without becoming familiar with the zone in which they are released; this constitutes a worst case scenario that is not representative of a normal outward and return flight by the foraging bees). The dose of insecticide added to the physical effort of flight is therefore liable to cause the death of the individuals rather than a sub-lethal effect of disorientation. **In this regard, it is very important to mention the fact that the experimental protocol does not answer this fundamental question: do the bees not return to the hive because they are disoriented (the foraging bees lose their way and finally die because of their exclusion from the colony) or do they die in the minutes which follow their release in the field because of excessive exposure to the insecticide?**

It is fundamental to recall here that the evaluation of the eco-toxicological risk of a substance is based, in an immutable way, on a comparison between the observed effects and the exposure doses. The evidence of a sub-lethal effect

[1] Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (apis meillifera, Bombus app. and solitary bees) EFSA Journal 2012; 10(5);2668

which is produced does not as such present any kind of alarm signal in the absence of a comparison with the exposure levels that can be genuinely envisaged under practical conditions.

There are certain studies, all of them submitted to, and evaluated by, ANSES within the framework of the application file for the AMM for Cruiser OSR for which the sub-lethal effects were the subject of particularly close monitoring:

- study of the return to the hive (Van der Ohe, 2001)[2] ;
- study of trophallaxis (Van der Ohe, 2001);
- study of the foraging behavior in a tunnel (Schur, 2001);
- intensity of foraging, development of the colony, sensitivity to illnesses in the context of the pluriannual monitoring of colonies under open field conditions (Hecht-Rost, 2009).

Among the studies cited, the study by Von der Ohe (2001) of return to the hive is of particular importance. This study in fact explores in precise details the same sub-lethal effects as those which were studied by Henry et al. in their experiment. This study which uses a marking technique other than RFID chips, enabled the success of the return flight of foraging bees exposed to thiamethoxam and then released at a distance of 500m from their hive to be estimated. Significantly, Von der Ohe, unlike Henry et al., administered the dose of thiamethoxam over distinctly longer periods than that devoted to "force feeding" in the experiment by Henry et al. and also respected the underlying eco-toxicological principle which consists in studying the effects of different concentrations of thiamethoxam.

Independently of the elements submitted in support of the AMM file, teams of researchers also explored the sub-lethal effects of thiamethoxam. Thus, Hassani et al. (2008)[3] and Aliouane et al. (2009)[4] followed in the laboratory the effects of exposure to thiamethoxam on purely sub-lethal parameters such as the extension of the proboscis, sensitivity to sugar and water, motricity and memory of bees.

In all these studies, sub-lethal effects were only observed in relation to much higher doses than those which are likely to be encountered under practical conditions.

In a similar spirit, two scientific studies have recently been published (Schneider et al., 2012[5] , Carayon et al., 2012 [6]). They showed sub-lethal effects of oxalic acid and

[2] Von der Ohe W. (2001a): Report on the study on the feeding of honey bees (*Apis mellifera L.*) with thiamethoxam (CGA 293343). 1. Testing of return flight ability. 2. Feed consumption and exchange (Trophallaxis), Niedersächsisches Landesinstitut für Bienenkunde, Celle, Germany. Unpublished report No. 99125/02/BHCE and 99125/02 BLCE.

[3] El Hassani, A, M. Dacher et al. (2008): "Effects of sub-lethal doses of acetamiprid and thiamethoxam on the behavior of the honey bee (*Apis mellifera*)". Archives of Environmental Contamination and Toxicology 54(4); 653-661.

[4] Aliouane, Y., A, K. el Hassani et al. (2009): "Subchronic exposure of honey bees to sub-lethal doses of pesticides: effects on behavior". Environmental Toxicology and Chemistry 28 (1): 113-122

[5] Schneider, S., D. Eisenhardt et al. (20120: "Sub-lethal effects of oxalic acid on *Apis mellifera* (Hymenoptera: Apidae): changes in behavior and longevity" Apidologie 42(2):218-225.

[6] Carayon et al. (2012): "Effects of thymol on the behavior of bees *Apis mellifera*" Presentation to the 42nd GFP Congress, 30 May-1 June 2012, Poitiers

thymol on *Apis mellifera*. That being so, must the use of these two substances which are commonly employed by bee keepers to combat *Varroa destructor* be immediately banned?

The fact of the matter is that only an assessment of the risk comparing the effects to the levels to which the bee may be exposed enables an assessment to be made as to whether sub-lethal effects can or cannot be observed under natural conditions.

b. Potential exposure to heavy doses of thiamethoxam

In toxicology, as in eco-toxicology, the determination of a toxic dose rests on three fundamental criteria: (i) the concentration of the substance in the source of contamination; (ii) the duration of exposure and (iii) the total dose ingested per unit of time. The study by Henry et al. is not representative of the reality of the practical use of Cruiser OSR and of the potential exposure of foraging bees.

First of all, it is a well-known fact that the concentration in the source of contamination determines in large measure the bio-availability of the substance in the organism. Thus, at the exaggeratedly high concentrations used by Henry et al. (30 times higher than the concentrations in the nectar presented in the Cruiser OSR file and between 47 and 165 times higher than the concentrations measured in the various oilseed rape nectars treated with Cruiser OSR and analyzed by ANSES in 2012), it is impossible to determine whether the limit membranes of the bee, more specifically the digestive tract, respond in an identical manner. For instance, are the mechanisms which regulate the passage of a xenobiotic such as thiamethoxam identical? With such wide concentration differences, how can the results obtained in the study by Henry et al. be scientifically extrapolated to those potentially observed under practical conditions at considerably lower exposure levels?

Moreover, the duration of exposure is itself highly unrealistic: the bees have in fact absorbed a toxic dose in a matter of minutes under the experimental protocol of Henry et al. However, in the risk assessment made by ANSES, the theoretical worst case scenario would cause the bee to be exposed to one-half of the dose used by Henry et al. over a foraging time of just under 11 hours. Because of the rapid "force feeding" in the laboratory, a straightforward transposition of the observed effects to those resulting from real exposure following natural daily foraging on a treated oilseed rape crop is impossible.

Finally, the dose of 1.34 ng of thiamethoxam/bee is distinctly higher than the dose which may in fact be observed in the field. In the first place, it is twice as high as the dose chosen as being the worst case scenario in the theoretical calculations performed by ANSES on the occasion of the assessment of the risk to bees arising from the Cruiser OSR preparation. It is even 4 to 13 times higher than the doses which might be calculated from the samples of floral nectar taken from winter oilseed rape made in 2012 by CETIOM and analyzed by ANSES.

These values show that the maximum theoretical levels calculated by ANSES on the basis of the values stated by Rortais are distinctly higher than those which may be encountered under real conditions. It is worth noting that each parameter used by

Rortais must be regarded as being its maximum value. However, if we work only with two realistic parameters (rate of sugar in the nectar and thiamethoxam concentration in the nectar), the dose used in the study by Henry et al. already appears to be highly excessive. And if we take other maximum parameters assumed by Rortais et al. (2005)[7] at their real value (example: daily flight duration and energy requirement of the bee), the dose employed by Henry et al. in the experiment would appear to be even more excessive.

ANSES cites exceptional conditions under which such a level might be measured. This possibility could be mathematically envisaged in the case of the nectars of certain oilseed rape varieties which are particularly low in sugar. In these hypothetical cases, the bee is assumed to consume more nectar to achieve the energy requirements needed for its flight; concomitantly, it is assumed to absorb more thiamethoxam. Now, as the Opinion quite rightly points out, questions may be asked about the genuine attractiveness of such oilseed rape nectars.

Many studies in fact show the preference of the bees for nectars which have the highest sugar content (for example, Scheiner et al. 2004[8]). Thus in reality the colonies in the presence of oilseed rape with nectar which has a low percentage of sugar would point their foraging bees away from this crop, even if it is within easy reach, to other sources with a higher nutritional potential even if this change implies a longer flight distance (work by TD Seeley[9]). It should likewise be noted that the sugar concentrations in the nectar from the CETIOM samples amount to between 25% and 67% and that the authors of the publication Henry et al., to justify the choice of their dose, take account of the very low levels of sugar in the nectar which are encountered only with one variety of oilseed rape and then only at the end of the flowering season.

For all these reasons, the conditions of exposure of the foraging bees in this experiment are altogether unrealistic and excessive and the effects observed in the study cannot be regarded *de facto* as representative of what might be observed in the case of bees foraging on an oilseed rape crop treated with Cruiser OSR.

c. Validity of the study in terms of the risk assessment

The inclusion of new experimental protocols in the official guidance documents with a view to their use for the purpose of the assessment of the risk of phyto-pharmaceutical products is effected according to a rigorous procedure. This includes a number of compulsory steps beginning with the identification of the interest of performing tests on a specific subject and concluding with the validation by the *ad hoc* expert groups (CEB at national level or OECD internationally) of the chosen study protocol.

[7] A. Rortais, G. Arnold, M.P. Halm, F. Touffet-Briens (2005) "Modes of honey bees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees". Apidologie (Celle) 36,71

[8] Scheiner et al. (2004): Sucrose responsiveness and behavioral plasticity in honey bees (*apis mellifera*)" Apidologie 35: 133-142

[9] Seeley TD (1986): "Social foraging by honey bees: how colonies allocate foragers among patches of flowers". Behav. Ecol Sociobiol. 19: 343-354

The study by Henry et al. did not follow the different validation phases indicated in the scientific position of EFSA. In fact, before being accepted by the scientific community and subsequently integrated into the risk assessment models, a method must undergo a whole battery of tests to demonstrate its robust character and above all its replicability.

This phase known as *ring-testing* enables international experts (scientific groups of the OECD in this particular instance) to judge the pertinence of the method employed to respond to the initial objective, to make improvements and adjustments which might prove necessary and, finally, to arrange for its integration into the risk assessment models.

Moreover, it is interesting to note that a national expert group, the bee methodology group of the CEB, mandated by the DGAL to develop methods for the assessment of risks to bees, is currently working on the development of a sub-lethal experimental protocol designed to study the impact of a phyto-pharmaceutical substance on the return of foraging bees to the hive. The first phase of the work of this group consisted in drawing up a list of the different experimental approaches enabling an answer to be given to this question. The experimental protocol of Henry et al. is simply one of the options available among a number of other scientific methods. It is therefore possible that the CEB methodology group may, following scientific exchanges between the members of the group, end up by proposing a method which differs from that of Henry et al. (or even an adaptation of that same method). That being so, how much weight should be given to the results obtained in an experiment with an inappropriate protocol?

In that sense ANSES concludes as follows: "*The experiments should be continued on the basis of RFID technology with varied levels of exposure so as to approximate more closely to the doses to which the bees are commonly exposed and with a more detailed study of the consequences of the effects observed individually on the dynamic of the bee colony.* ***This work would enable a study protocol which would permit a better description of the sub-lethal effects of exposure to neonicotinoids to be validated; that protocol might then be taken into account in the future evolution of European regulatory provisions***."

The opinions of ANSES and EFSA in any case call attention to the imperfections of the study by Henry et al. The remarks can be grouped together under four sub-headings:

- <u>One single study with a single dose</u>: when the risk (i.e. the sub-lethal and/or lethal toxicity) of a chemical compound is to be studied, the standard practice in toxicology and in eco-toxicology is to examine a number of different doses to determine with the greatest possible accuracy the eco-toxicological behavior of the molecule (estimate the gap between the dose which has no effect and the dose with a 10% effect or the dose with a 50% effect, for example). This is clearly indicated in the scientific opinion of EFSA: "*The scientific community recommends conducting the assessment of sub-lethal effects both at sub-lethal and lethal doses/concentrations (Desneux et al. 2007)*." That is not the method chosen by Henry et al. who in fact studied just

one single dose, so rendering the interpretation of the observed effects highly debatable and delicate.

Similarly, one of the foundations of scientific research resides in the repetition of the experiments to take due account of biological variability. In the framework of this experiment, many variable factors may, however, be envisaged: genetic differences between colonies of bees, climatic conditions at the time of the experiment, point in time during the season at which the experiment is conducted; all of these factors may interact to influence the sensitivity (lethal or sub-lethal) of the foraging bees to thiamethoxam. On the contrary, however, the authors of the experiment Henry et al. draw conclusions from a single experiment as to the effects observed, without taking the precaution of repeating this study with the same protocol to confirm the validity of their observations.

- An unrealistic exposure: this point has already been dealt with previously in this document, but it is worth recalling that the authors administered over a very short period of time (a few minutes) a dose of thiamethoxam which is twice as high as that regarded as the maximum by ANSES for daily foraging over a period of eleven hours. ANSES and EFSA both take the view in their respective opinions that the levels administered to the bees are distinctly higher than those routinely encountered. This fact has been confirmed by the monitoring program put in place in cooperation with CETIOM, the results of which are summarized in the ANSES opinion. Moreover it is highly probable that the very exceptional conditions referred to by ANSES under which the bees might be exposed to levels in the order of those used by Henry et al. could not be reproduced under real conditions. The fact is that the few varieties of oilseed rape which produce a nectar weak in sugar during a limited period of their flowering would in all probability not be visited often by the bees. As mentioned by ANSES (and by the Minister in his press release of 29 March 2012) it would be desirable to reproduce this experiment with a more realistic exposure consisting in leaving the bees free to forage on fields of oilseed rape treated with Cruiser OSR in order to confirm or invalidate the results obtained by Henry et al. with a highly artificial exposure (ANSES opinion: "*These studies should therefore be continued in order to verify whether the effects on the return to the hive such as those observed have a medium or long-term impact on the development and survival of the colony.*").

- An inappropriate statistical analysis: the opinion of ANSES is categorical on this point: "*The precise binomial test is a test which permits comparison of an observed percentage with a theoretical percentage. The comparisons made in the article are of a different nature because the two percentages compared are the outcome of field observations in the treated group on the one hand and in the reference group on the other. An adequate test to compare two observed percentages is the precise Fisher test. In view of the relatively high numbers of bees in the different groups concerned, a Chi2 test would also be appropriate.*"

- An unrepresentative model: to estimate whether the effects observed in the framework of their single experiment could represent a risk under practical

conditions, the authors of the study confined themselves to the use of a mathematical model to estimate whether the proportion of foraging bees which failed to return to the hive could have an impact on the survival of the colony. In its Opinion, ANSES points out that the model showing the dynamic of the bee populations is a "*very simple theoretical model (which) therefore cannot be used to simulate the dynamic of a bee population in situ.*" In other words, the authors apply an unrepresentative theoretical model to the results of an experiment based on an unrealistic exposure. The definitive conclusions resulting from this approach are not scientifically admissible. ANSES points that out in the following words: "*The results obtained with the methodology used in the article by Henry et al. (2012), however innovative it may be, cannot at the present juncture be reliably interpreted in terms of the effects on the future of the colonies under real conditions of exposure corresponding to bee keeping and farming practice, because of the fact that the model used is inappropriate to anticipate the impact on the population dynamic.*"

3. Conclusion

The explanations set out above highlight the many shortcomings of the experiment and therefore raise serious doubts as to the validity of this study and *a fortiori* its possible use for risk assessment purposes. In view of the totally unambiguous conclusions reached by ANSES and EFSA in reply to the questions which were put to them, it appears very surprising, and, to say the least, unfounded and contrary to any scientific and rational approach, to envisage the withdrawal of the product Cruiser OSR on the basis of these preliminary results. In fact, future regulatory assessments may lead in the first instance to the selection of better study protocols (or to far-reaching amendments of the method used) and, secondly, the simple repetition of this self-same study might give contrary results which would invalidate the conclusions of this study in the near future, so making a possible withdrawal of the product completely unjustified.

Moreover, how can such an intention of withdrawal be justified at a time when EFSA is continuing its assessment at the request of the European Commission to which the French Minister of Agriculture has referred the matter and in view of the fact that the conclusions of this Agency are not expected to be available before the end of the year 2012?

Moreover, a withdrawal would be a negation of the reality in the field and of the observations made over a period of many years of the use of Cruiser OSR in the main European countries without any incident. The withdrawal of this product will in no way help to combat the excessive mortality of bees. The map of the mortalities recorded in France (study by ITSAP – Technical and Scientific Institute for Beekeeping and Pollinization) does not correspond to the zones in which seed protection products are used. On the other hand, this same study mentions a close link between the quality of the fight against the acarian Varroa and the level of mortality. Anyone who claims to be convinced of the contrary will have to explain the reasons why in a country like Australia, where products belonging to the neonicotinoid family are widely used but Varroa and the associated viruses (DWV, KBV...) are absent, the bee mortalities are regarded as being of a perfectly normal

level. Similarly, it may be noted that in a country like Madagascar bee mortalities have become worrying since Varroa first made its appearance in 2009.

Finally, we wish to call your attention to the fact that there is no real alternative to Cruiser OSR; may we also remind you of the economically intolerable consequences for oilseed rape growing in France, especially at this point in time, of the withdrawal of Cruiser OSR. To that end we attach figures presenting the likely impact on the different stakeholders in this industry.

For all the above reasons, and more specifically those which are supported by scientific data, we ask you not to withdraw the authorization for the commercial sale of the product Cruiser OSR.

We remain, Director-General,

Yours faithfully,

[redacted]

Annex to the observations submitted by the Syngenta Agro SAS company in response to the notification of the intention to withdraw the authorization for the commercial sale of the product Cruiser OSR®, AMM No. 2100180

Economic aspects

This summary of the economic consequences of a withdrawal of the AMM for Cruiser OSR® takes account of the fact that no genuine alternative for seed protection or for leaf treatment to safeguard the yield of oilseed rape crops exists in France.

Cruiser OSR in fact provides complete protection against diseases and insects while the existing solutions for both seed protection and leaf protection are only partially effective. Only one insecticide other than Cruiser OSR is for instance permitted for seed protection purposes, and then only against the large flea beetle, but its toxicological classification does not allow it to be mixed with fungicides. The farmer is then confronted with a difficult problem: that of choosing between a diseased plant or a plant infested with insects.

Moreover, without the protection provided by Cruiser OSR, losses of plants before normal growth are frequently observed and in that case a leaf application has actually no effect.

Mention must also be made of the recrudescence of viruses whose transmission takes place at a very early stage by aphids (whose control by existing insecticides is increasingly inadequate) and results in yield losses which may be as high as 40%.

The analysis made by us shows that fields treated with Cruiser OSR enable an additional yield of two quintals per hectare to be obtained as compared to fields protected with the best "alternative" solutions. Under conditions which are less favorable for oilseed rape, these losses may represent on average up to 10% of the crop or 3.5 quintals for an average yield over the past three years of 35 quintals per hectare. Taking account of all the costs of the two methods of protection, this represents a net margin for the farmer ranging from 105 euros (low hypothesis) to 171 euros (high hypothesis).

Given the plans to sow oilseed rape treated with Cruiser OSR, the prejudice suffered by farmers for the year 2013 (2012 sowing) would range from 140 million euros (low assumption) to 230 million (high assumption) if the permit for commercial sale were to be withdrawn.

In addition, there will be the following loss of earnings:

- for Syngenta: 10.7 million euros (products and seeds);
- for the other seed suppliers: 21.5 million euros including 7 million euros accounted for by seeds already treated in 2011 and currently held in stock.

If the French decision on withdrawal were to be confirmed and if the other European countries were to adopt the same position on all neonicotinoids used on oilseed rape, the prejudice suffered by the farmers would range from 645 million euros (low assumption) to 1 billion euros (high assumption), given the fact that a great majority of European oilseed rape crops are protected today with neonicotinoids.

The total loss of income for plant health companies and seed suppliers would then be 69 million euros, including 15 million euros for Syngenta alone.

A prohibition in France, if not followed in the other European countries, would have a dramatic consequence for the oilseed rape seed production branch which would rapidly be relocated elsewhere with a net loss of GDP amounting to 72 million euros and substantial consequences for employment.

The ban on the use of neonicotinoids on oilseed rape throughout the European Union would then represent a loss of GDP amounting to nearly two billion euros per year (assuming an average crop reduction of 10%).

This prejudice would be repeated every year until the potential arrival of solutions with a performance similar to that of Cruiser OSR.

We naturally remain at your disposal to provide details of the way in which the above figures have been calculated.

[redacted]

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9 July 2012

The Rt Hon James Paice, MP
Minister of State for Food and Farming
Department of Environment, Food and Rural Affairs
Nobel House
17 Smith Square
London
SW1P 3JR

Dear Minister,

Further to my letter of 15th June, 2012, I write to inform you that the French Minister of Agriculture has now formally announced his decision to withdraw the national registration of our product CRUISER® OSR in France based on his belief that the product impacts bee health.

In taking this decision, the French Minister has based his position on a single experimental study, authored by Michael Henry at INRA, which used unrealistic, laboratory-based, dosing rates at levels which could only impair the ability of bees to return to their hives.

A number of Member State regulatory agencies have already concluded that the dosing levels in this study do not provide a realistic representation of the exposure levels to bees in-field.

Indeed, as outlined in my previous letter, there is nothing in the written report from France's own advisory agency, ANSES, to support their minister's decision. We also believe that the minister has chosen to ignore the comprehensive arguments we submitted to him in defense of CRUISER® OSR. For your reference I have enclosed/attached a copy of the dossier we submitted to the Minister in France in response to his announcement of the intention to ban our product.

Neonicotinoid-based seed treatments for oilseed rape, (which includes CRUISER® OSR), are one of the most advanced forms of crop protection technology and have been used safely for over 10 years on approximately seven million hectares across the EU without incident. The product protects up to 30% of yield. The loss of this technology across the EU would cost farmers and consumers up to €1 billion, undermining the production of safe and affordable food.

Given that the French minister's decision potentially contravenes the existing European regulatory processes regarding the authorization and marketing of seed treatment crop protection products in Europe we understand that the French government will now look to increase efforts to push the European Commission to propose an EU-wide suspension on all neonicotinoid seed treatments for oil seed rape.

I urge you to resist pressure from the French government in the coming weeks and look to the scientific evidence and your own advisory agencies to make an assessment.

In addition, as you know, EFSA has an ongoing review of the risk assessment framework for pesticides and bees and should complete this by the end of 2012. Any action to suspend or ban neonicotinoid-based seed treatments before this review is published would be premature and serve only to undermine the robustness of the EU regulatory process.

For your information, we are seeking an urgent legal injunction in France against the Minister's decision given the complete absence of validated scientific opinion and the practical experience of the safety of CRUISER® OSR in use. I will contact you again to provide details of this legal process in the coming weeks.

Finally, please be assured that Syngenta is committed to sustainable agriculture and the essential role played by pollinating insects like bees. We are involved in a number of studies designed to better understand bee health in the context of productive agriculture and have already put in place substantive solutions, including the provision of habitat and nutrition for bees through the Operation Pollinator project, which are today making a real difference to their well-being.

Please do not hesitate to contact me should you require any further information at this time.

Yours sincerely