CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for bees for the active substance fipronil[1]

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ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment for the active substance fipronil and provide conclusions as regards the risk to bees. In this context the conclusions of EFSA following the peer review of the risk assessment for bees for the active substance fipronil are reported. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. The conclusions were reached on the basis of the evaluation of the currently authorised uses of fipronil applied on a variety of crops in Europe. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and scientific publications including data available at EU and national level, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

KEY WORDS

Fipronil, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Fipronil was included in Annex I to Directive 91/414/EEC on 1 October 2007 by Commission Directive 2007/52/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

The specific provisions of the approval were amended by Commission Directive 2010/21/EU, to permit only use as a seed treatment and only where the seed coating is performed in professional seed treatment facilities, which must apply the best available techniques to ensure that the release of dust during application to the seed, storage and transport can be minimised, and where adequate drilling equipment is used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

In accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data, in August 2012 the European Commission requested the EFSA to perform an evaluation of the active substance fipronil and deliver its conclusions on the risk assessment for bees, in particular with regard to the acute and chronic effects on colony survival and development, taking into account effects on bee larvae and bee behaviour, and the effects of sublethal doses on bee survival and behaviour.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing data submitted for the approval of the active substance at EU level and for the authorisation of plant protection products containing fipronil at Member State level, taking into account the available EFSA Conclusion (EFSA Scientific Report (2006) 65, 1-110), and the EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (EFSA Journal 2012;10(5):2668). In addition, the recent EFSA statement 'Assessment of the scientific information from the Italian project "APENET" investigating effects on honeybees of coated maize seeds with some neonicotinoids and fipronil' (EFSA Journal 2012;10(6):2792), and related scientific publications, as well as any further data from studies, research and monitoring activities considered relevant were also taken into account in the current evaluation.

Several data gaps were identified with regard to the risk to honey bees from exposure via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation fluid for the authorised uses of fipronil as a seed treatment. Furthermore, the risk assessment following exposure to residues in insect honeydew, the risk assessment from plant and soil metabolites (except soil photolysis metabolites), the risk assessment from exposure to residues in succeeding crops or weeds and the risk assessment for pollinators other than honey bees could not be finalised on the basis of the available information. A high risk was indicated or could not be excluded in relation to certain aspects of the risk assessment for honey bees for some of the authorised uses. For some exposure routes it was possible to identify a low risk for some of the authorised uses.

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BACKGROUND

Fipronil was included in Annex I to Directive 91/414/EEC[3] on 1 October 2007 by Commission Directive 2007/52/EC[4], and has been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. The peer review leading to the approval of this active substance was finalised on 3 March 2006, as set out in the EFSA Scientific Report (2006) 65 (EFSA, 2006).

The specific provisions of the approval were amended by Commission Directive 2010/21/EU[8], to permit only use as a seed treatment and only where the seed coating is performed in professional seed treatment facilities, which must apply the best available techniques to ensure that the release of dust during application to the seed, storage and transport can be minimised, and where adequate drilling equipment is used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

In view of the various studies and research activities carried out in recent years, and taking into account the outcome of the EFSA statement on the assessment of the scientific information from the Italian project "APENET" investigating effects on honey bees of coated maize seeds with some neonicotinoids and fipronil (EFSA, 2012), the European Commission decided to consult the EFSA in accordance with Article 21 of Regulation (EC) No 1107/2009. By written request, received by the EFSA on 9 August 2012, the European Commission requested the EFSA to perform an evaluation of fipronil and provide conclusions as regards the risk to bees, in particular with regard to the acute and chronic effects on colony survival and development, taking into account effects on bee larvae and bee behaviour, and the effects of sublethal doses on bee survival and behaviour.

A consultation on the evaluation and preliminary conclusions of EFSA on the risk assessment for bees was conducted with Member States via a written procedure in January - February 2013. The draft conclusions drawn by EFSA, together with the points that required further consideration in the assessment as well as the specific issues raised by Member States following the consultation were discussed at the Pesticides Peer Review Experts' Meeting 100 on ecotoxicology in February 2013. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report. A further consultation on the final conclusions arising from the peer review of the risk assessment for bees took place with Member States via a written procedure in March 2013.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing data in relation to the risk assessment for bees submitted for the approval of the active substance at EU level and in support of the product authorisations at Member State level. In addition, the available EFSA Conclusion (EFSA, 2006), as well as the EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (EFSA PPR, 2012) and the recent EFSA statement 'Assessment of the scientific information from the Italian project "APENET" investigating effects on honey bees of coated maize seeds with some neonicotinoids and fipronil' (EFSA, 2012) were also taken into account. Furthermore, the scientific publications linked to the

[3] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[4] Commission Directive 2007/52/EC of 16 August 2007 amending Council Directive 91/414/EEC to include ethoprophos, pirimiphos-methyl and fipronil as active substances. OJ L 214, 17.8.2007, p. 3-8.

[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.

[6] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

[7] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

[8] Commission Directive 2010/21/EU of 12 March 2010 amending Annex I to Council Directive 91/414/EEC as regards the specific provisions relating to clothianidin, thiamethoxam, fipronil and imidacloprid OJ L 65, 13.3.2010, p.27-30.

"APENET" project as well as any further data from studies, research and monitoring activities considered relevant were also taken into account in the current evaluation.

A key background document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised during the peer review. The Peer Review Report (EFSA, 2013d) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the study evaluation notes[9],
- the report of the scientific consultation with Member State experts,
- the comments received on the draft EFSA conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

[9] As no Draft Assessment Report was available in the context of this peer review, the studies and available data submitted by the applicant and / or made available by the Member States were evaluated by EFSA and summarised in a document titled 'study evaluation notes'.

CONCLUSIONS OF THE EVALUATION

There is no clear definition to consider fipronil as a systemic molecule. Section B.3.1.2.2 of the DAR (France, 2004) states that fipronil is not considered to exhibit a systemic activity, however it was indicated that fipronil can provide some degree of protection at an early stage of infestation against insects feeding on the foliage. This suggests that some uptake (of the parent fipronil and/or metabolites with insecticidal action) by the plants is likely, which was also indicated by the assessments of supervised residue trials on different plants.

Studies published in the open literature and studies available in the dossier (see section 3) indicated that residues of fipronil (parent and metabolites) are taken up by sunflower seedlings and can be distributed within the plant. Root uptake of substances seems to occur for all organic micropollutants and seems to be mainly a function of the octanol-water partition coefficient and the molar mass (Sur *et al.*, 2012). Therefore it cannot be excluded that fipronil or its soil metabolites are transported to the upper parts of the plants via the roots. Therefore, even if it had been assumed that fipronil has a low potential for systemic distribution in plants, the risk from exposure via nectar and pollen, honeydew or guttation fluids was considered in these assessments.

Fipronil has numerous plant and soil metabolites (summarised in Appendix D). These are potentially relevant for the risk assessment for honey bees via different routes of exposure, e.g. via residues in nectar and/or pollen and via residues in guttation fluid. Limited information regarding their toxicity to honey bees was available. Only acute toxicity data were available for two of them, which indicate that they are highly toxic to honey bees (see Table 1). In the available higher tier effect studies and residue trials (performed for bee relevant matrices) only a limited number of metabolites were investigated. Furthermore, the LOQ in the available studies may not have been sufficiently low for a risk assessment for honey bees given the toxicity of the parent substance, fipronil. It is noted that the metabolite RPA 200766 was detected in bee honey stomachs at the level of 0.0033 mg/kg in a field study performed with treated sunflower seeds (see section 3). Moreover, the metabolite RPA 200761 (degradation product of RPA 200766) was detected in sunflower florets at the level of 0.0014 mg/kg (France, 2006).

The risk assessment for metabolites was further discussed at the Pesticides Peer Review Experts' Meeting 100 (February 2013). The metabolites concerned are:

- for soil: RPA 200766, MB 46136 and MB 45950 (the two soil metabolites MB 46513 and RPA 104615 are not relevant because they are soil photolysis metabolites, not formed in soil from seed treatment and incorporated uses).

- for plants: RPA 200766, RPA 200761, RPA 105320, MB 46136, MB 45950, RPA 104615 and MB 46513.

The experts at the meeting agreed that the available data are not sufficient to characterise the potential exposure to all the metabolites.

Overall, a data gap was identified to address the exposure and hence the risk to bees from plant and soil metabolites, except the soil photolysis metabolites (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses) for all the uses evaluated, except crops grown and maintained in permanent glasshouses and where the growing media is not spread in the agricultural environment. In addition, a further data gap was identified in section 7 to address the risk to bees from residues in succeeding crops or weeds occurring in the field ensuring that all persistent soil metabolites are addressed.

Limited information was available for pollinators other than honey bees. The biology, behaviour and ecology of bumble bees and other pollinators differ from honey bees and therefore special consideration in a risk assessment is necessary. For example, exposure via soil or plant materials used for nesting materials might be a potential route of contact exposure for some bumble bee or solitary

bee species. Oral exposure may also differ since the nectar, pollen or water requirement for other pollinators is different to that of honey bees. Currently it is unclear whether these routes of exposure are covered by other risk assessments, such as via dust drift. The risk to pollinators other than honey bees should be further considered. A data gap is therefore concluded for further information to address the risk to pollinators (other than honey bees) for all the uses evaluated, except crops grown and maintained in permanent glasshouses and where pollinators are not used for pollination.

Some Member States' experts highlighted during the peer review that in their respective countries there are ongoing assessments for authorisations for uses other than seed treatments, i.e. for use as granules to be applied to potatoes during the sowing. In relation to this use, some studies were made available to EFSA on the potential exposure from dust, guttation and honeydew. However, it was agreed that these studies are not relevant for the currently authorised uses as a seed treatment due to potential different conditions of exposure and therefore they were not considered in this conclusion. However there are no indications of higher concerns in these studies in comparison to the studies evaluated for the seed treatment uses.

1. Toxicity endpoints

1.1. Acute toxicity

Table 1 summarises the available acute laboratory toxicity data for fipronil and the metabolites MB 46136 and RPA 200761.

Table 1 Available laboratory toxicity data for fipronil and the metabolites MB 46136 and RPA 200761

Test substance	Toxicity endpoint	Species	Value[1]	Reference
fipronil	Acute oral LD_{50}	*Apis mellifera*	**0.00417 µg/bee**	EFSA (2006)
MB 46136	Acute oral LD_{50}	*Apis mellifera*	0.0064 µg/bee	EFSA (2006)
RPA 200761	Acute oral NOEL	*Apis mellifera*	0.29 µg/bee[2]	EFSA (2006)
fipronil	Acute contact LD_{50}	*Apis mellifera*	**0.00593 µg/bee**	EFSA (2006)

[1] Values highlighted in **bold** were used for risk assessment

[2] based on a single nominal concentration of 10.3 mg/kg (NOEC) equivalent to 0.29 µg/bee (NOEL)

1.2. Chronic toxicity

Aliouane *et al.,* (2009) investigated chronic mortality following contact and oral exposure of fipronil to honey bees under laboratory conditions (0.1 ng/bee/day and 0.01 ng/bee/day). Doses of fipronil at 0.1 ng/bee/day resulted in 100 % mortality following 1 week of exposure (both orally and via contact exposure). The control mortality after 11 days was comparable to the level of mortality observed in the 0.01 ng/bee/day test groups. It is noted that the dose of 0.1 ng/bee/day (where 100 % mortality was observed) is approximately 42 and 60 times less than the acute oral and acute contact LD_{50} values, respectively, which may indicate higher sensitivity following chronic exposure.

Decourtye *et al.,* (2005) investigated chronic mortality following oral exposure of fipronil to honey bees under laboratory conditions. Fipronil was administered in sucrose solution at concentrations of 9, 4.5 and 2.2 µg a.s./L, which are equivalent to doses of 0.3, 0.15 and 0.075 ng/bee/day. The mortality after 11 days of exposure was 91.1, 87.3 and 40.6 % at doses of 0.3, 0.15 and 0.075 ng/bee/day, respectively. The mortality in the control was 6.6 %. It is noted that these doses are 14, 28 and 56 times less than the acute oral LD_{50} value, respectively, indicating higher sensitivity following chronic exposure.

The chronic mortality endpoint to be used for the first-tier risk assessment was discussed at the Pesticides Peer Review Experts' Meeting 100. Several concerns were raised for both literature studies

(Aliouane *et al.*, 2009 and Decourtye *et al.*, 2005) regarding the exposure, i.e. no analytical check of the test concentrations of fipronil was performed, which may question the reliability of the test concentration and hence the reliability of the exposure. However, currently there is no standard guideline for this type of tests. Overall, the experts considered the endpoint of 0.075 ng/bee/day from Decourtye *et al.*, 2005 (as a surrogate 10-day LC_{50} expressed in mass), as the most appropriate value available for the first-tier risk assessment.

1.3. Endpoints based on sublethal effects

Several studies investigating the sublethal effects of fipronil to honey bees were reported in the literature.

Decourtye *et al.*, (2011) investigated the effects on homing failure and foraging activity following acute oral exposure of fipronil to honey bees using honey bee tracking (RFID technology) under semi-field conditions. Doses of 0.06 ng a.s./bee and 0.3 ng a.s./bee did not have an effect on the rate of bees returning to the hive nor was there an effect on the daily pattern of foraging flights. However, doses of 0.3 ng a.s./bee reduced the number of foraging flights per bee during the first 24 hours after exposure. In addition, doses of 0.3 ng a.s./bee had a significant prolonging effect on the time taken for the honey bees to return to the hive; this effect was apparent for 3 days after exposure. No analytical check of the test concentrations of fipronil was performed, which may question the reliability of the test concentration and hence the reliability of the exposure.

Colin *et al.*, (2004) investigated also the effect of oral exposure to fipronil on the foraging activity of honey bees under semi-field conditions. Fipronil was applied at a concentration of 2 µg a.s./kg in syrup at feeder stations placed within the tunnel. The results indicated a strong reduction in the number of foragers using the feeder station after 4 days, compared with an untreated control. In addition, there was an increase in the number of inactive forager bees at the feeder. The study authors also reported other clinical signs of intoxication of the honey bees (details of the observations were not provided). The study authors proposed that the disruptive motor activity of the bees was affected by sublethal doses which consequently meant that the bees were no longer able to forage. No analytical check of the test concentrations of fipronil was performed, which may question the reliability of the test concentration and hence the reliability of the exposure.

Aliouane *et al.*, (2009) investigated a number of sublethal effects following a chronic contact and oral exposure of fipronil to honey bees under laboratory conditions (0.1 ng/bee/day and 0.01 ng/bee/day). Doses of fipronil at 0.1 ng/bee/day resulted in 100 % mortality following 1 week of exposure, however the sublethal effects were followed with the dose of 0.01 ng/bee/day. Decreased responsiveness to stimulation with sucrose solution was observed after oral exposure. Following contact exposure the bees were observed to spend increased time immobile, and the water consumption was also increased. Therefore, no chronic NOEC for behavioural parameters could be derived. As cited in Aliouane *et al.*, (2009), in a previous study (El Hassani *et al.*, 2005) the locomotor activity was not affected following acute (single dose) contact or oral exposure.

Decourtye *et al.*, (2005) investigated learning performance (PER test) following chronic oral exposure of fipronil to honey bees under laboratory conditions. Fipronil was administered in sucrose solution at concentrations of 9, 4.5 and 2.2 µg a.s./L, which are equivalent to doses of 0.3, 0.15 and 0.075 ng/bee/day. Due to 91.1 % mortality at the dose of 0.3 ng a.s./bee/day, the behavioural assessments were only performed for the doses of 0.15 and 0.075 ng/bee/day. At both dose levels a statistically significant effect on the learning performance of the bees was observed in comparison to the untreated control. (There was a reduction in the response of the treated bees compared with the response of the bees in the untreated control; responses were: 7.1 % in the honey bees tested at 0.15 ng/bee/day, 27.2 % at 0.075 ng/bee/day, whereas the control honey bees had a response of 56.2 %.)

Sublethal effects of fipronil were investigated within the APENET project. Tests, such as learning and olfactory memory with the PER test, or on homing failure and foraging behaviour in the field were conducted. However, these studies were not considered valid by EFSA (see EFSA, 2012). For

example, as regards the PER test, on the basis of the information provided it was not possible to guarantee that the protocol was developed under fully controlled conditions and with appropriate statistical testing; as regards the homing failure and foraging test, incompleteness of the description of these studies and their results did not allow for a proper assessment of the methodology and data presented. No further data were available for reconsidering the previous EFSA evaluation, therefore the outcome of the research was not reconsidered in this conclusion. Overall, for risk assessment purposes a sublethal endpoint of 0.06 ng a.s./bee (as a surrogate NOEL) from Decourtye *et al.,* (2011) was proposed. This value was based on a reduced number of foraging flights per bee and on the time taken for the honey bees to return to the hive at the next (highest) dose of 0.3 ng/a.s./bee. This endpoint was also agreed at the Pesticides Peer Review Experts' Meeting 100 as appropriate for a first-tier risk assessment. However, it was noted that, given the increased sensitivity of bees to fipronil after repeated exposure, the use of an acute endpoint for sublethal effects to address the risk for colony survival and development after chronic exposure was considered as a major uncertainty.

1.4. Toxicity endpoints on brood

No data investigating the effect of fipronil under laboratory conditions were available and therefore no endpoint for brood could be derived.

1.5. Additional information from the literature

Information from the open literature indicated a potential synergistic effect following simultaneous exposure to fipronil and *Nosema ceranae* (Aufauvre *et al.,* 2012 and Vidau *et al.,* 2011). It was noted that no analytical check of the test concentrations of fipronil was performed, which may question the reliability of the test concentration and hence the reliability of the exposure. A further study performed under field conditions (Bernal *et al.,* 2011) in Spain was available and investigated the combination of *Nosema ceranae* and *Varroa destructor* together with fipronil. The study was performed on sunflowers grown from fipronil treated seeds. It is noted that the sunflower pollen constituted only 40 – 77 % of the collected pollen being brought back to the hives. No residues of fipronil or its metabolites were detected above the LOD (0.0002 mg/kg) in pollen or beebread (the LOQ was 0.0005 mg/kg). However, residues of a number of other insecticides were detected in pollen taken from the sunflowers. The study author concluded that the combination of *Nosema ceranae* and *Varroa destructor* could lead to colony death even without exposure to fipronil residues (above the LOD). The study authors also concluded that the loss observed in apiaries located close to sunflower crops was similar to that in apiaries situated in forested areas with wild vegetation.

In addition, Roat *et al.,* (2012) investigated the toxicity of fipronil to the Africanized honey bee (a hybrid of *Apis mellifera*). The LD_{50} after topical application was 1.06 ng/bee and the LC_{50} after acute oral administration was 1.27 ng/µl diet. Sublethal effects were observed at 0.01 ng/bee per day (repeated exposure). No analytical check of the test concentrations of fipronil was performed, which may question the reliability of the test concentration and hence the reliability of the exposure.

2. Risk from contamination of neighbouring crops via dust drift

2.1. Acute risk assessment

Screening step

A quantitative risk assessment was not available and currently no agreed guidance or trigger value is available to assess the risk to honey bees from dust drift. However, Appendix J of EFSA PPR (2012) suggests to use the full dose (active substance application rate in terms of g a.s./ha) as a very worst case screening step. The use of the full dose is on the basis of 10 % dust deposition in the neighbouring areas (a conservative value on the basis of experience gathered by Petri dish measurements in the last few years) multiplied by a factor of 10 to account for the interception by the three-dimensional structured plants. The screening assessments considering the whole in-field application rate for the highest and lowest application rates authorised in the EU are illustrated in Table 2. The acute oral and acute contact toxicity endpoints for fipronil are taken from Table 1.

Table 2 HQ values calculated using the in-field application rate for the lowest and highest application rates authorised in the EU, and laboratory LD_{50} values

	Acute oral	**Acute contact**
LD_{50} (µg a.s./bee)	0.00417	0.00593
Hazard Quotient for the lowest application rate (5 g a.s./ha)	1199	847
Hazard Quotient for the highest application rate (110 g a.s./ha)	26379	18644

The resulting HQ values are high and therefore the screening risk assessment is not sufficient to indicate a low risk.

Tier 1 risk assessment using the default deposition values proposed in draft guidance documents

A first-tier risk assessment can be performed using the default deposition values for dust drift reported in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012[10]. It is important to note that these values are taken from a draft guidance document and therefore may be subject to change at a later date, therefore care should be taken with the interpretation of the following risk assessments. Furthermore, the default values in the 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012' are based on pneumatic drillers, which are fitted with a deflector. For the authorised seed treatment uses of fipronil (Appendix A), no dust drift deposition values were available for crops other than maize. Therefore, a tier 1 risk assessment could not be performed for sunflower or vegetable crops.

The following risk assessments for maize are based on the highest and lowest application rates authorised in the EU for maize. The same acute oral and acute contact LD_{50} values used in the screening assessment (Table 2) were used. Table 3 presents the resulting acute HQ values for honey bees foraging in adjacent vegetation following dust emission during the drilling of maize.

Table 3 Tier 1 HQ values calculated using the proposed default deposition values in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012' for the highest and lowest application rates authorised in the EU for maize

Crop	**Parameter**	**Lowest application rate authorised in the EU**	**Highest application rate authorised in the EU**
Maize	Application rate (g a.s./ha)	17.5	44
	% deposition (adjacent vegetation)	7	7
	Predicted off-field deposition rate (g a.s./ha)	1.225	3.08
	Acute oral HQ	293.8	738.6
	Acute contact HQ	207.6	522.0

No agreed trigger value is available for the interpretation of the tier 1 HQ values. EFSA PPR (2012) proposed a trigger value of 50, which is in line with the current trigger for a first-tier risk assessment for foliar sprays. However, currently this value has not been agreed for use in honey bee risk assessment from dust exposure.

As indicated in Table 3, the resulting tier 1 HQ values for maize indicate a high acute risk to honey bees foraging in adjacent vegetation following dust emission during drilling.

[10] European Commission; Draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012; DRAFT, 8 March 2012.

The deposition values used to calculate the above HQ values (Table 3) were considered within the draft EFSA guidance document for bees[11] (under development at the time of this evaluation) and were amended by taking into account landscape factors when contamination of nectar and pollen is estimated (i.e. by considering the oral exposure). The default deposition values for adjacent crops proposed are approximately 50 % of those used in the risk assessments presented Table 3. Consequently, the resulting HQ values would be 50 % lower, however, the outcome of the risk assessment would remain unchanged.

2.2. Chronic risk assessment

In addition to the HQ calculations to cover acute effects, EFSA PPR (2012) suggests calculating a chronic ETR_{adult} (exposure to toxicity ratio) between the amount of residues that may be ingested by an adult bee in 1 day and the 10-day LC_{50} value. This assessment would cover the potential chronic effects. To conduct such calculations, the uptake rate of a bee should be estimated after foraging on crops exposed to dust drift. Currently no official guidance is available for these estimations, however, if the residues in nectar and pollen, and the daily consumption of bees were known, then the daily uptake of fipronil could be estimated. Information on the residue levels in nectar and pollen occurring after dust drift to adjacent vegetation is not available, therefore the first-tier chronic risk assessment for situations when bees forage on a crop exposed to dust drift emitted during the drilling procedure cannot be performed.

2.3. Risk assessment for bee brood

EFSA PPR (2012) also suggests calculating an ETR_{larvae} between the amount of residues that may be ingested by a larva in 1 day and the no observed effect level (NOEL) for larvae. Currently no official guidance is available for these estimations, however, if the residues in nectar and pollen, and the daily consumption of bees were known, then the daily uptake of fipronil could be estimated. Information on the residue levels in nectar and pollen occurring after dust drift to adjacent vegetation is not available. Furthermore, as discussed in section 1.4, no endpoint for brood was available. Therefore the first-tier risk assessment for bee brood for the situations when bees forage on a crop exposed to dust drift emitted during the drilling procedure cannot be performed**.**

2.4. Risk assessment using higher tier effects studies

No higher tier studies were available for fipronil within the dossier provided by the applicant as regards the dust emission and the effects on honey bees.

Within the APENET project, several trials were performed to measure the dust dispersal of some neonicotinoids and fipronil during the sowing of treated maize seeds. Some of these trials were conducted with a precision pneumatic seeder machine equipped with deflectors further modified. These trials were considered in EFSA (2012). Due to some deficiencies in the reporting of the results, EFSA concluded that a detailed analysis of these results could not be performed, but some general trends could be observed. As also reported in published papers (Pochi *et al.*, 2011 and Biocca *et al.*, 2011), the application of air deflectors on pneumatic drilling machines resulted in a reduction of dust drift deposition. In particular, the dust and therefore the deposition of residues in the off-crop area decreased with distance; however, no decrease with distance was apparent in the air concentration. For fipronil, at soil level an overall average reduction of 60.7 % was estimated while the reduction of concentration in air was not statistically significant (0.6 %) (Biocca *et al.*, 2011). This was attributed by the authors to the very fine fractions of the dust. In Marzaro *et al.*, (2011) and Tapparo *et al.*, (2012), it is reported that the aerial contamination is likely to be the most relevant route of exposure rather than contact with the adjacent vegetation. However, in experiments performed in Germany with some neonicotinoids (see EFSA, 2013a, 2013b and 2013c), it was concluded that the relevant route of exposure is foraging in contaminated areas. Marzaro *et al.*, (2011) also concluded that it is important to investigate the mechanism through which honey bees come into contact with the dust to enable

[11] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

effective mitigation measures to be applied. In another experiment within the APENET project (Pochi *et al.*, 2012), the application of an innovative air recycling/filtering system resulted in a substantial reduction in the active substance concentration in air. However, the authors concluded that no data were available on the quantity of the active substances actually retained by bees during the flight, with regard to the air concentrations.

2.5. Conclusion on the risk via dust drift

For **maize** a high acute risk was identified at the first-tier risk assessment using default deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012'. The deposition values used to calculate the tier 1 HQ values for maize (see Table 3) were considered within the draft EFSA guidance document for bees[12] and were amended by taking into account landscape factors when contamination of nectar and pollen is estimated (i.e. by considering the oral exposure). The default deposition values for adjacent crops proposed are approximately 50 % of those used in the risk assessments presented in section 2.1 (Table 3). Consequently, the resulting HQ values would be 50 % lower, however the outcome of the risk assessment would remain unchanged. It should be noted however, that the assessments presented above are conservative assessments and focus on a relatively narrow strip downwind at the edge of the treated field. In practice, this assessment indicates that forager honey bees or other pollinators occurring in this strip are at high risk (e.g. via direct contact to dust) and may be able to carry considerable residues back to the hive (for social bees). Bees present beyond this strip or foraging upwind during the sowing will be considerably less exposed. Also, the risk from dust drift is dependent on some landscape factors, such as the occurrence and distribution of attractive plants around the drilled area or the machinery used (e.g. the type of drilling machine or the use of deflector systems to mitigate emission).

No chronic risk assessment or a risk assessment for bee brood could be performed for maize and therefore the assessment is not finalised. Some experiments conducted within the APENET project indicated a potential for reducing the dust emission of fipronil at soil level during the sowing of treated maize seeds. However, no data were available to indicate the impact of such a reduction on bees in terms of both acute and long-term risks.

For the **other field crops**, the risk assessments could not be finalised, therefore a high risk from the exposure to dust originating from the drilling procedure could not be excluded.

For some crops, for which it was indicated that the seeds are sown in permanent glasshouses, such as leeks (authorised uses in the Netherlands), due to negligible exposure, the risk to bees via dust drift exposure is considered negligible.

In conclusion, a data gap was identified to address the risk (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses) to honey bees for situations where bees forage on vegetation exposed to dust drift emitted during the drilling procedure for **all the uses** evaluated, **except for crops sown in glasshouse**.

It is important to highlight that Aliouane *et al.*, (2009) reported that a chronic contact exposure endpoint to a sublethal dose of 0.01 ng a.s/bee/day affected the locomotor activity. Such an effect was not observed in a previous study (El Hassani *et al.*, 2005), when the same dose level was administered both orally and topically but following a single dose (acute exposure).

3. Risk via translocation in plants – residues in nectar and pollen

Fipronil is authorised for use in maize, sunflower and different leafy, stalk or bulb vegetables (see Appendix A) in seven European countries. These vegetables do not flower or they are normally harvested before flowering (unless they are grown for seed-production purposes). Therefore these

[12] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

crops will pose a low risk to bees via this route of exposure. However the flowers of sunflower and maize are attractive and nectar and/or pollen may be collected by bees (pollen only for maize as maize does not produce nectar).

Information on the residue levels occurring in nectar and pollen was reported in the DAR (France, 2004), however the majority of the data were summarised in the Final Addendum (France, 2006), from studies in the dossier and from the open literature. Several residue measurements of sunflower matrices were available for the parent fipronil and for its metabolites MB 46513, MB 45950, MB 46136 and RPA 200766. These trials were conducted in different regions of France and one trial in Spain with fipronil treated sunflower seeds, or with soil treatment, or the seeds of the previous crop were treated with fipronil (in the latter two cases untreated sunflower crop was drilled). None of the nectar or pollen samples indicated any residues above the LOQ. The LOQ used in these studies were 0.002, 0.001 and 0.0005 mg/kg. The exception to this was a residue of 0.0033 mg/kg of the metabolite RPA 200766, which was detected in the honey bee stomach. Regarding maize pollen, there were also residue measurements for fipronil and its metabolites available from northern and southern France, Germany and Spain. The majority of the samples did not indicate any residues above the LOQ of 0.0005 mg/kg. However for the parent fipronil, there were a few positive samples indicating residue levels up to 0.0064 mg/kg, which were derived from a subsample (the average value from the same subsample within the residue trial was 0.0023 mg a.s./kg). No residues of the metabolites MB 46513, MB 45950, MB 46136 and RPA 200766 were detected above the LOQ (0.0005 mg/kg). A similar situation was also observed for residues in guttation droplets, where fipronil was detected only in a small number of samples; the metabolites (MB 46136, MB 45950 and MB 46513) were not detected above the LOQ (see section 6).

It is noted that for both crops (maize and sunflower) there were additional residue trials conducted in Spain, however the results of these trials were considered to be invalid and therefore they were not taken into account further. It should be noted that high residue levels were detected in some samples in these studies. However, due to contamination of the control samples (up to 0.111 mg/kg in sunflower pollen), the residue values for the treatment samples were not considered to be reliable. The validity of these studies were discussed at the Pesticides Peer Review Experts' Meeting 100 and the experts agreed to identify a data gap for the applicant to explain the high residue levels found in these studies. This data gap was already indicated in the previous EFSA Conclusion on fipronil (EFSA, 2006), but no further information was available.

Studies published in the open literature (Aajoud *et al.*, 2008, Raveton *et al.*, 2007) indicated that residues of fipronil (parent and metabolites) are taken up by sunflower and can be distributed within the plant. Conversely, these studies also indicated that the absorption of fipronil residues via the roots from the treated seeds was not high. Moreover, the level of residues accumulated in the inflorescence was very low, only 0.06 % of the quantity applied to the seed in the study by Aajoud *et al.*, (2008).

Studies were available in the dossier from the applicant on the translocation of fipronil and its metabolites in plants, which were summarised in the Final Addendum (France, 2006). A study on sunflower (Final Addendum B.7, Huang, M.N. 2003b) indicated that the uptake and translocation of radioactive fipronil was low when applied to sunflowers as a seed treatment formulation. Only 2 - 3 % of the residues on the treated seed at planting were translocated to the aerial parts of the plants collected at two immature harvests. This amount increased slightly to 4 % by the final harvest. The majority of the residues remained in the lower leaves and stalk. These results are consistent with those observed in studies performed on maize, sunflower, cotton, sugar beet and wheat, where it was noted that only 0.8 to 4.5 % of the applied radioactivity was taken up in the aerial parts of the plants. The majority of the residues in the sunflower leaf and stalk samples collected at two immature harvests were fipronil. Other residues included metabolites RPA 200766 and MB 46136, with the remaining residues composed of trace amounts (0.1 - 0.6 % TRR) of metabolites RPA 200761, MB 45950, MB 46513 and MB 45897. The metabolite profile was similar in the stalk and leaf samples. In the mature florets (second immature harvest), only one metabolite was identified: RPA 200761 was found to be 40 % of the floret residues with a concentration of 0.0014 mg/kg. The remaining residues in the

florets consisted of three other metabolites (0.04 % TRR), which were polar in nature. There was no quantifiable radioactivity at retention times by HPLC, where fipronil and the metabolites MB 46513, MB 45950, RPA 200766 or MB 46136 were expected to appear.

This information supports the data set for residues obtained for sunflower and maize. Overall, it might be concluded that there is a low potential for fipronil and its metabolites to occur or accumulate in pollen and/or nectar of the seed treated crops. However, the presence of some traces of residues (i.e. below the LOQ) cannot be excluded.

3.1. First-tier acute risk assessment

EFSA PPR (2012) suggests calculating an ETR_{acute} (exposure to toxicity ratio) value taking into account the amount of residues that may be ingested by a bee in 1 day via contaminated pollen and/or nectar and the oral LD_{50}. Currently no practical guidance is formally available regarding the estimation of the ingestion rate of residues or regarding the comparison of this estimation with the toxicological endpoint. However, if the residues in nectar and pollen and the daily consumption of bees are known, the daily uptake of fipronil or its metabolites can be estimated.

Regarding the feed consumption, EFSA PPR (2012) reported data for different castes of bees. As a worst case for adult honey bees, the following scenarios were considered:

- 32 - 128 mg sugar/day for a forager bee;
- 34 - 50 mg sugar/day and 6.5 - 12 mg pollen/day for a nurse bee.

Since instead of nectar consumption, the energy needs of the bees are reported (sugar/day), the daily nectar consumption needs first to be estimated. For this estimation, the sugar content of nectar needs to be considered. The sugar content of nectar is crop-specific and highly dependent on several biotic and abiotic factors. For example, Nicolson concluded (Nicolson, 2008) that honey bees prefer sugar concentrations of 30 – 50 %, but in practice they collect from a much wider range of nectars, which was measured by Seeley (1986) to be 15 – 65 % in nectar loads being brought into a single colony. Once the nectar consumption is estimated, the daily residue uptake of a bee can be calculated by using the following formulae:

$$RI_{forager} = \frac{Rn \times Cn}{1000}$$

$$RI_{nurse} = \frac{(Rn \times Cn) + (Rp \times Cp)}{1000}$$

Where: $RI_{forager}$ is the residue intake by a forager bee expressed in µg/bee/day
RI_{nurse} is the residue intake by a nurse bee expressed in µg/bee/day
Rn is the residue level in nectar in mg/kg
Rp is the residue level in pollen in mg/kg
Cn is the consumption of nectar in mg (mg/bee/day)
Cp is the consumption of pollen in mg (mg/bee/day)

Sunflower

Based on the data submitted by the applicant and Member States, fipronil is authorised in 5 EU countries for use as a seed-dressing under the product names of ‘Cosmos 500 FS’ or ‘Regent 500 FS’, with the application rates between 5 and 18 g a.s./ha (see Appendix A). No definitive residue value in nectar or pollen was available since all the residue measurements indicated residue levels below the LOQ. This indicates that the oral exposure of bees collecting these feed items is potentially low. However, since some exposure via this route cannot be completely excluded, residue intake

calculations were conducted using an LOQ as a surrogate of the worst case residue levels. Considering the low potential of fipronil residues to be present in the relevant matrices (see section 3), the lowest available LOQ of 0.0005 mg/kg was considered further in the exposure estimations, irrespectively of the seed dressing rates used in the residue trials or the application rates authorised in the EU (i.e. no RUD values were derived).

Assuming 15 % as a realistic worst case estimation for sugar content of the nectar to be relevant for risk assessment, the nectar consumption was estimated to be 213 - 853 mg/bee/day for a forager and 227 - 333 mg/bee/day for a nurse bee. Assuming a residue level equal to the LOQ (i.e. 0.0005 mg/kg for both nectar and pollen) and the higher values for consumption, the residue intake (RI, expressed in ng/bee/day) was calculated to be < 0.427 ng/bee/day for a forager and < 0.173 ng/bee/day for a nurse bee. Comparing these intake rates with the acute oral LD_{50} of 4.17 ng/bee, ETR_{acute} values of < 0.102 and < 0.041 were derived for forager and nurse bees, respectively.

Maize

Based on the data submitted by the applicant and Member States, fipronil is authorised for use as a seed-dressing in the same 5 EU countries under the same product names as for sunflower, but with the application rates between 17.5 and 44 g a.s./ha (see Appendix A). The highest residue level measured in maize pollen (for parent fipronil) was 0.0064 mg/kg (= 6.4 µg/kg, the average value from the same subsample was 2.3 µg a.s./kg). In this trial, the seed drilling rate was 73 000 seeds/ha and the recommended seed dressing rate was reported to be 55 ml of 'Regent TS'/unit of 50 000 seeds. It was also reported that the product ('Regent TS') contained nominally 500 g fipronil/L. From these data, an application rate of 40.15 g fipronil/ha or a seed dressing rate of 0.55 mg/seed was estimated. By expressing the above residue level as RUD, (in terms of g a.s./ha), on the basis of the relevant information (application rate and residue level from the residue study), residue levels in maize pollen were calculated to be 2.79 and 7.01 µg/kg, for the lowest and highest authorised application rates, respectively. It may be argued that the seed dressing rate could be more appropriate for estimation of the likely residues for the authorised uses and therefore this has also been considered in the following assessment. In 4 out of the 5 EU countries, the authorised seed dressing rate was reported to be 0.35 mg a.s./seed (one Member State did not indicate this value in terms of mg a.s./seed). By expressing the above residue level as RUD (in terms of mg a.s./seed), on the basis of the relevant information (seed dressing rate and residue level from the same residue study), a residue level of 4.07 µg/kg was estimated (using the same approach as above) for the seed dressing rate of 0.35 mg a.s./seed.

Using the estimated residues and the higher value for consumption, the residue intake (RI, expressed in ng/bee/day) for a nurse bee was calculated to be between 0.033 – 0.084 ng/bee/day for the lowest and highest application rates (g a.s./ha), respectively. Comparing these intake rates with the acute oral LD_{50} of 4.17 ng/bee, ETR_{acute} values of 0.008 and 0.020 were derived, respectively. Considering the residue estimated for the seed dressing rate, the estimated residue intake (RI) was 0.049 ng/bee/day and the ETR_{acute} value is 0.012. It is noted that since maize has no nectar, a residue level of 0 mg/kg was considered in these calculations for nectar consumed by a nurse bee.

The approach followed in the risk assessment (i.e. the use of the lowest LOQ value as a surrogate of the residue level in pollen and nectar for sunflower and the highest residue data on pollen for maize) was discussed at the Pesticides Peer Review Experts' Meeting 100. As regards the use of the LOQ of 0.0005 mg/kg as a surrogate residue value, the experts agreed that it is a sufficiently conservative approach. As regards the residue in maize, where the maximum residue value was taken from a subsample, it was considered that the average value from the same trial (i.e. 0.0023 mg/kg) would be more appropriate given that the majority of the data indicated a residue level below the LOQ. However, since the residue trials were conducted in a limited area (mainly in France), the residue data set was considered not sufficient to cover all of the EU maize growing area situations for the authorised uses of fipronil. Therefore, to account for some of the uncertainty over the residue data, the conservative approach of using the maximum detected value was considered appropriate.

It should be noted that there is no agreed trigger value for the interpretation of the risk assessment and therefore it is not possible to conclude the acute risk assessment on the basis of the first-tier ETR values.

3.2. First-tier chronic risk assessment

EFSA PPR (2012) suggests calculating the value of ETR_{adult} taking into account the amount of residues that may be ingested by an adult bee in 1 day and the LC_{50} value. The LC_{50}, as suggested by EFSA PPR (2012), should originate from a 10-day dietary study on adult bees. No such LC_{50} value was available for fipronil or its metabolites, but endpoints from similar published studies were available for the parent fipronil (see section 1.2). On the basis of these available studies a chronic LC_{50} of 0.075 ng/bee/day (Decourtye *et al.*, 2005) was agreed at the Pesticides Peer Review Experts' Meeting 100 for a first-tier risk assessment.

Using this endpoint and the same estimations for the exposure (RI values) as described above for the acute risk assessment, chronic ETR_{adult} values were calculated for sunflower and maize. These values are presented in Table 4.

Table 4 Chronic ETR_{adult} values for the authorised uses on sunflower and maize considering the endpoint of 0.075 ng/bee/day

Crop	Residue intakes (RI) ng/bee/day	ETR_{adult} for forager bee	Residue intakes (RI) ng/bee/day	ETR_{adult} for nurse bee
sunflower	< 0.427	< 5.69	< 0.173	< 2.31
maize, based on the lowest and highest application rate (17.5 and 44 g a.s./ha)	-	n.a.	0.033 - 0.084	< 0.44 - 1.2
maize, based on the seed dressing rate of 0.35 mg/seed	-	n.a.	0.049	< 0.65

n.a.: not applicable

For sunflower, the ETR values for both the nurse and forager bee are > 1. For maize (highest application rate), the ETR value for the nurse bee is also > 1 using the application rate but < 1 using the seed dressing rate. These ETR values therefore may indicate that the exposure exceeds the toxicity value. It should be noted that there is no agreed trigger value for the interpretation of the risk assessment when ETR values were < 1. Therefore, it is not possible to conclude the chronic risk assessment on the basis of the first-tier ETR values.

3.3. First-tier risk assessment for brood

EFSA PPR (2012) suggests calculating the value of ETR_{larvae} taking into account the amount of residues that may be ingested by a larva in 1 day and the no observed effect level (NOEL). However, no toxicological endpoint was available (see section 1.4), therefore no risk assessment for larvae could be performed.

3.4. Risk assessment for sublethal effects using first-tier exposure estimates

Currently there is no agreed testing strategy for the assessment of sublethal effects. Furthermore, it is not fully understood what type of sublethal effect could potentially lead to adverse effects on honey bee colonies. Nevertheless, sublethal effects were observed and reported in some studies, which are summarised in section 1.3. From these studies it was concluded that sublethal effects, such as decreased responsiveness to stimulation, can occur when bees are exposed to 0.01 ng/bee/day fipronil or above following chronic exposure (Aliouane *et al.*, 2009). When acute treatment (i.e. a single dose) was applied, bees tolerated the dose level of 0.06 ng/bee without showing effects on foraging

behaviour, but adverse effects on the foraging were observed at the treatment level of 0.3 ng/bee (Decourtye *et al.*, 2011). The latter endpoint was derived from a study which was conducted under semi-field conditions, while the previously mentioned endpoint of 0.01 ng/bee/day was derived from a laboratory study. The extrapolation of the endpoints derived from the laboratory study to the field is difficult and uncertain, while the endpoints from the semi-field conditions are likely to give a good representation of potential effects on colony survival and development. Therefore risk assessments using the same approach as for the acute and chronic assessments were conducted. In particular, the ratios were calculated between the residue intakes (RI) reported in sections 3.1 and 3.2, and the endpoint of 0.06 ng/bee, which, to some extent, can be interpreted as a NOEL for foraging behaviour. These calculations are illustrated in Table 5 and were performed only for forager bees and for the authorised uses on sunflower.

Table 5 Ratios between the residue intakes (RI) and the endpoint of 0.06 ng/bee where no effects on foraging behaviour were observed for the authorised uses on sunflower

Crop	Residue intakes (RI) ng/bee/day	Ratio for forager bee
sunflower	< 0.427	< 7.12

The calculated ratio value was > 1 and therefore may indicate that the exposure exceeds the toxicity value. Currently there are no agreed trigger values (or a risk assessment scheme) for sublethal effects. Therefore, it is not possible to conclude the risk assessment for sublethal effects on the basis of the above assessment.

At the Pesticides Peer Review Experts' Meeting 100, it was noted that, given the increased sensitivity of bees to fipronil after repeated exposure, the use of an acute endpoint for the risk assessment for sublethal effects was considered as a major uncertainty. The calculations in Table 5 do not cover all the sublethal effects that may be relevant for colony survival and development after chronic exposure.

3.5. Risk assessment using higher tier studies

Several relevant semi-field and field studies were available for sunflower and one semi-field study for maize. The majority of the studies were already reported in the DAR (France, 2004) and the Final Addendum (France, 2006), and evaluated at EU level (EFSA, 2006), but the studies have been reconsidered for the present conclusion in view of EFSA PPR (2012). A re-evaluation of all the available semi-field and field studies was reported in the 'Study evaluation notes' (EFSA, 2013d).

Studies on sunflowers

A total of 9 higher tier studies were available with fipronil treated sunflower seeds. Five of the studies were performed under semi-field conditions and 4 were field studies. One field test (Maurin G., 1999, field part) and one semi-field test (Maurin G., 2001) were not considered reliable for risk assessment, which was in line with the conclusion of the previous peer review.

The field studies aimed to investigate the effects on honey bees foraging on the treated crop grown from fipronil treated sunflower seeds. The investigations included effects on mortality, effects on bee brood, some sublethal effects and colony strength. Residue analyses in pollen, honey and nectar were also conducted. Bocksch 2009a was performed in Northern Spain (near Zaragoza) with the formulated product 'Regent 500 TS'. The seed treatment rate was 531.8 g a.s./100 kg seed and the application rate was 29.34 g a.s./ha. Bocksch 2009b was performed in Central-Eastern Spain (near Valencia), also with the formulated product 'Regent 500 TS'. The seed treatment rate was 531.8 g a.s./100 kg seed and the application rate was 31.65 g a.s./ha. A study by Schur (2005) was also performed in Central-Eastern Spain (near Valencia) and again used sunflower seed treated with the formulated product 'Regent TS'. The seed treatment rate was 538.6 g a.s./100 kg seed and the application rate was 33.97 g a.s./ha.

The authorised uses of fipronil for sunflower are up to a maximum of 18 g a.s./ha and therefore the application rate used in the studies covers the authorised uses of fipronil. With respect to the seed treatment rate, the authorised uses generally have a seed treatment rate of 0.2 mg/seed (with the exception of the authorised use of 'Cosmos 500FS' in the Czech Republic which has a seed dressing rate of 1.25 kg a.s./1000 kg seed (see Appendix A). The studies were reasonably well performed, however, as indicated in the 'study evaluation notes' a number of limitations were noted and the studies were not considered to meet all of the recommendations in EFSA PPR (2012) (e.g. a lack of pre-exposure mortality, a lack of survey of surrounding area, statistical analysis was performed for mean results only, etc.). Moreover, the assessments performed did not confirm exposure to the honey bees. With the exception of the metabolite RPA 200766, which was detected in nectar taken from forager bees in Bocksch 2009b, measured residues were less than the LOQ.

In Bocksch 2009a, on a few occasions a statistically significant effect on mortality was observed. Due to high control mortality the results should be interpreted with care. A potential effect on bee brood was noted, but it was not clearly attributable to the test item. In Bocksch 2009b, there were also a number of occasions where a statistically significant effect on mortality was observed. It was noted that 3 days after sowing the mortality in the control was very low. Similarly to Bocksch 2009a, a potential effect on bee brood was noted, but it was not clearly attributable to the test item.

In Schur 2005, the honey bee mortality in the control and the treatment hives was comparable. However, there was a noticeable difference in the foraging activity on the treatment plots compared to the control. Moreover, bee behavioural observations indicated a higher level of 'cleaning activity' in the treatment hives. The reason for the difference in foraging activity was not clarified but it was considered that it may be due to a repellent effect (or unfavourable nectar flow). There were no clear effects on bee brood, however further analysis is necessary to be able to draw definitive conclusions. Due to the very low foraging activity and consequently low potential for exposure, the results should be interpreted with care.

As regards the semi-field studies, the studies from Maurin G., 1999, (semi-field part) and Giffard H., 2001, in the DAR, it was concluded that there were no adverse effects on mortality, behaviour or colony development. However, the studies appear to have only been 9 or 10 days in length and therefore it was questionable whether the assessments were of sufficient length to allow for meaningful assessments on bee brood. In the study from Decourtye A., & Tisseur M. (2005), it was concluded in the DAR that no behavioural effects and no increase in honey bee mortality was observed. However, the study was considered by the RMS as not appropriate for assessing the effects on larvae development. In the study from Schur (2005) there was evidence of contamination of the controls (fipronil detected in control pollen in both trials), which raises doubts as to the reliability of the analytical results (indicating high residue levels). Therefore, the residues values were not used for the risk assessment presented in sections 3.1, 3.2 and 3.3. Effects on brood cannot be excluded as larva stage disappeared from all the treated tunnels, but also from one of the control hives (larvae also disappeared from a control hive that was used for residue analysis whereas the treatment hive contained larvae).

Studies on maize

Only one semi-field study was available for maize (Jeker, 2009). The study was performed with maize seed treated with 'Regent 500 TS' at a rate of 167.6 g a.s./100 kg seed. The application rate was 43.48 g a.s./ha. The authorised uses of fipronil for maize are up to a maximum of 44 g a.s./ha and therefore the application rate used in the study covers the authorised uses of fipronil. With respect to the seed treatment rate, the authorised uses generally have a seed treatment rate of 0.35 mg/seed (with the exception of the authorised use of 'Cosmos 500FS' in the Czech Republic which has a seed dressing rate of 1.25 kg a.s./1000 kg seed (see Appendix A)). It was noted that there was a slight, but statistically significant increase in mortality in the treatment group of the bee trap assessments. There was also a slight, but not statistically significant increase in mortality in the linen sheet assessments. No adverse effects on bee brood and colony strength were reported, however it is questionable

whether the length of the study and the frequency of the observations was suitable for a meaningful assessment for bee brood.

Overall interpretations from higher tier studies

Overall, clear effects were not observed in any of the studies (i.e. no large deviation from the control in any observed parameters). However, there were some indications of potential effects, such as increased forager mortality or a lack of larval stage of the brood. In one study (Schur, 2005 near Valencia), significant differences were observed in the foraging behaviour that might be attributed to some repellent effect. However, none of these cases could be attributed to exposure to fipronil with high certainty. In addition, it is noted that, where potential effects were indicated on some parameters of the treated colonies, all the effects appeared to be only transient. All studies were considered to have drawbacks, for example, one or more of the following: short exposure or short post-exposure follow-up period; a lack of pre-exposure investigations; a low number of replicates; a lack of information on colony health; food stock was not removed to ensure the use of freshly collected food; a lack of survey of the surroundings or evidence for attractive alternative food sources in the vicinity of the fields; a lack of pollen source analysis or analysis indicated relatively low ratio of relevant pollen type. Moreover, it should be noted that in the majority of the studies no residues in bee relevant matrices were detected above the LOQ and therefore understanding the actual level of exposure is difficult.

Therefore, the level of exposure to pollen and nectar of the seed treated plants was unclear and it was concluded that the available studies were not sufficient to demonstrate that the risk to bees was low for the use of fipronil as a seed treatment to sunflower. In the case of the study on maize, the measured residue levels in pollen were low (< LOQ) compared with the available residue data set.

Overall, considering the available higher tier studies for sunflower, it might be concluded that the studies encompassed a limited number of agricultural situations considered to be typical for Europe. However, whether any of these studies were realistic worst case, could not be proven. Furthermore, the representativeness and severity of the single study on maize could not be proven, considering its drawbacks.

3.6. Conclusion on the risk via translocation in plants – residues in nectar and pollen

A low risk was concluded for **all uses on vegetables** (see a list of these crops in Appendix A) as these crops cannot be foraged for pollen or nectar by bees. It is noted that this conclusion would not apply if these crops were grown for seed-production purposes (and therefore would be allowed to flower), outdoor.

Fipronil is also authorised for use on **sunflower** and **maize**, which are attractive crops for bees. Therefore first-tier risk assessments were conducted for these crops considering consumption of nectar and/or pollen by adult bees. The ETR values for acute exposure were < 0.041 for nurse bees and < 0.102 for forager bees for sunflower, and 0.008 and 0.020 for nurse bees for maize for the lowest and highest application rates, respectively. This indicates that the calculated intake (oral exposure) is at least about one order of magnitude less than the acute toxicity (oral LD_{50}) for these crops (margin of safety is about 10 or more for sunflower and about 50 or more for maize). However, the chronic ETR values for sunflowers, calculated on the basis of the LOQ and a surrogate LC_{50}, were above 1 (which means that a very worst case exposure is higher than the toxicity endpoint). For maize, the ETR values were less than 1 for the lowest application rate or when the seed dressing rate was considered. The first-tier risk assessment for sublethal effects on forager bees performed for the uses on sunflowers indicated that the exposure exceeds the toxicity value, i.e. the ratio between the potential exposure (calculated using the LOQ) and the NOEL for foraging behaviour was above 1. However, it is important to note that the risk assessment is based on an endpoint derived following administration of a single dose. Given the increased sensitivity of bees to fipronil after repeated exposure, this should be further considered. It must be noted that residues of the metabolite RPA 200766 were detected at a level of 0.0033 mg/kg in the bee honey stomach in a sunflower field study. This is considered to

confirm the potential for exposure of honey bees to the metabolite RPA 200766 and could be more relevant than exposure to the parent substance, fipronil. No toxicity data were available for the metabolite RPA 200766 and therefore a quantitative risk assessment could not be performed (see general data gap on metabolites in section on 'Conclusions of the evaluation').

No endpoint for first-tier risk assessments for bee brood was available, therefore this assessment could not be conducted.

It is highlighted that the available first-tier calculations for sunflower and maize are considered as worst case assessments for several aspects. In the residue intake estimations, worst case nectar and pollen consumptions and a worst case sugar content of nectar was considered. Furthermore, factors such as metabolism in bees or dilution by foraging in uncontaminated areas were not considered. Regarding the residue levels, also worst case values were used. In case of maize, only a few samples were positive for fipronil or its metabolites (only two trials), while all the other trials indicated residue levels < LOQ. The residue value used in the risk assessments originates from a subsample that indicated considerably higher residue level than the average of all the samples from the trial, i.e. the worst case residue value from the whole data set was selected and used for the risk assessments. Regarding sunflower, the LOQ was used as a surrogate of determined residue levels. Overall, these data indicate that the likelihood of the occurrence of high residue levels (e.g. > 0.0005 mg/kg) in sunflower or maize is generally low. Therefore, considering the available data set for residues, these assessments represent rather non-typical (rare) situations. Furthermore, it should also be noted that the majority of the residue values originate from France, with a few additional data from Germany and Spain. Therefore the representativeness of the used data sets to other regions of Europe is uncertain. It is acknowledged that a relatively low LOQ (0.0005 mg/kg) for fipronil has been achieved. However, it is noted that the LOQ may not be sufficiently low given the toxicity of fipronil to honey bees.

The used endpoints for chronic toxicity or for sublethal effects are also uncertain since currently no harmonised or internationally recognised test guidelines are available for these aspects.

Higher tier (semi-field and field) studies were available for sunflower and maize. However, all of these studies had drawbacks (see section 3.5), and therefore they were not sufficient to demonstrate that the risk to bees was low for the use of fipronil as a seed treatment in sunflower and maize.

Overall, on the basis of the available data and assessments, a data gap was identified to further address the risk following the ingestion of contaminated nectar and/or pollen (i.e. the acute risk and the long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses) in sunflower and maize. The data gap, identified in the previous EFSA Conclusion (EFSA 2006), to address the contamination of the control residue samples in the bee tunnel study in Spain (BASF DocID 2005/1006522; Schur A. 2005 and BASF DocID 2005/1006523; Schur A. 2005) was maintained.

4. Risk via translocation in plants – residues in honeydew

Potentially honey bees could forage on insect honeydew present in treated crops. It may be argued that insect honeydew will not be present in crops grown from fipronil treated seed as the seed treatment may prevent crop pests, which produce honeydew. However, no information was available to demonstrate that the seed treatment will prevent the formation of insect honeydew. Therefore, with the information available, it cannot be excluded that there is a potential high risk to bees from foraging on insect honeydew. A data gap is therefore concluded for further information to address the risk to honey bees foraging on insect honeydew (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses) for all the uses evaluated except crops grown and maintained in glasshouses.

5. Risk via residues in flowering weeds present in the treated field

Theoretically, residues of fipronil and its soil metabolites in weeds in the treated field could also be a route of exposure to honey bees. However, the risk via this route of exposure (during the period when the treated crop is present) was considered to be negligible as weeds will not be present in the field when the crop is sown and considerable uptake via the roots is unlikely as the substance is concentrated around the seed. However, as indicated in section 7, a data gap is identified to address the risk to honey bees from fipronil and its metabolites via translocation in succeeding crops or weeds.

6. Risk via translocation in plants – guttation

As discussed in the section on 'Conclusions of the evaluation', it cannot be excluded that fipronil is translocated in plants and therefore there is the potential for residues of fipronil and the metabolites to occur in guttation fluid which is extruded by plants grown from the treated seed. The exposure to honey bees from residues in guttation fluid will be primarily dependent on two factors – the concentrations of fipronil and its metabolites in the guttation fluid and the extent to which honey bees utilise guttation fluid.

During the Pesticides Peer Review Experts' Meeting 97 (November 2012) the German expert provided feedback on several experiments conducted in Germany investigating the potential effects to honey bees from exposure to guttation fluid (Frommberger, M. *et al.*, 2012; Pistorius, J. *et al.*, 2012; Joachimsmeier *et al.*, 2012). The experiments were conducted with plant protection products containing a systemic pesticide (clothianidin) and therefore only general conclusions on the occurrence and use of guttation fluid is considered relevant to the risk assessment for plant protection products containing fipronil. The German expert reported that different crops varied in terms of frequency and intensity of guttation events. Peak residues were reported in early growth stages. In the experiments conducted in Germany it was reported that there were several other water sources in the area surrounding the colony and the guttation droplets were only present for a limited time. It was noted that the potential collection of guttation fluid poses a different risk than foraging on nectar and pollen, where the bees will be attracted to the crop.

Residues of fipronil and its metabolites

Tapparo *et al.*, (2011) investigated the concentration of fipronil, thiamethoxam, imidacloprid and clothianidin in guttation fluid produced in maize plants grown from treated seed in pots under glasshouse conditions. The fipronil treated seeds were treated with the formulated product, 'Regent', at a seed dressing rate of 0.5, 0.75 and 1 mg a.s./seed. No residues of fipronil above the LOD (5.1 µg/L) were detected in the guttation fluid produced by the maize plants (the LOQ was 16 µg/L). Conversely, residues of thiamethoxam, imidacloprid and clothianidin were detected in the guttation fluid (up to 346 mg/L for imidacloprid, 102 mg/L for clothianidin and 146 mg/L for thiamethoxam). It is noted that Tapparo *et al.*, (2011) did not investigate residues of fipronil metabolites. Moreover, the LOD (5.1 µg/L) and the LOQ (16 µg/L) for the detection method used by Tapparo *et al.*, (2011) was relatively high.

Two studies are available where residues of fipronil and the metabolites MB 46136, MB 45950 and MB 46513 were investigated in the guttation fluid produced by sunflower and maize plants under field conditions (Garcia (2011), 2011/1120991 and Garcia (2011), 2011/1120992, see Study evaluation notes, EFSA, 2013d). Both studies were performed in Spain and used seed treated with 'Regent TS' at 2150 mg a.s./kg seed. The guttation fluid was sampled when the crop was at growth stages of BBCH 11 – 71 for maize and BBCH 12 – 55 for sunflower. No residues of fipronil or the metabolites MB 46136, MB 45950 and MB 46513 were detected above the LOQ (0.5 µg/kg) in the guttation fluid produced by sunflower plants. In the majority of samples of guttation fluid taken from maize plants, residues of fipronil or the metabolites MB 46136, MB 45950 and MB 46513 were also not detected above the LOQ (0.5 µg/kg) (i.e. 12 out of 14 samples from two trials). However, in one maize trial (out of two trials) residues of fipronil were detected at BBCH 15 (2.1 µg/kg) and BBCH 23 (0.8 µg/kg). Samples of guttation fluid from earlier growth stages were not analysed.

Although the residues detected in the maize plants in Garcia (2011, 2011/1120991) are not of similar magnitude to those detected for the neonicotinoid active substances in Tapparo *et al.*, (2011), the detected residues confirm that, under certain conditions, fipronil can be taken up by plants and extruded in the guttation fluid.

It should be noted that only two field studies were available which investigated the concentration of fipronil and the metabolites MB 46136, MB 45950 and MB 46513, and both studies were conducted in Spain. Given the influence of environmental conditions of the potential for plants to guttate, extrapolation to other locations is highly uncertain. Furthermore, although the studies were reasonably well performed, there is uncertainty as to whether the studies were performed under worst case conditions, i.e. those conditions which are likely to result in the highest concentrations in the guttation fluid.

It is also noted that the maize seed used in Garcia (2011, 2011/1120991) was at a rate of 2150 mg a.s./kg seed, which was estimated to be equivalent to 0.51 mg/seed. With the exception of 'Cosmos 500FS' in the Czech Republic, the authorised products for use on maize are treated at a rate of 0.35 mg a.s./seed. 'Cosmos 500FS' in the Czech Republic is authorised at a rate of 1.25 kg a.s./1000 kg seed (=1250 mg a.s./kg,) and therefore the rate tested in the Garcia (2011, 2011/1120991) study could be considered to cover the authorised uses.

The sunflower seed used in Garcia (2011, 2011/1120992) was also at a rate of 2150 mg a.s./kg seed, which was estimated to be equivalent to 0.16 mg a.s./seed. Again, with the exception of 'Cosmos 500FS' in the Czech Republic, the authorised products for use on sunflower are treated at a rate of 0.2 mg a.s./seed, therefore the rate tested in the Garcia (2011, 2011/1120992) study is less than in the majority of the authorised uses. 'Cosmos 500FS' in the Czech Republic is authorised at a rate of 1.25 kg a.s./1000 kg seed (=1250 mg a.s./kg) and the rate tested in the Garcia (2011, 2011/1120991) study could be considered to cover the authorised use of Cosmos 500FS' in the Czech Republic.

6.1. First-tier risk assessment

Currently there is no agreed approach for a first-tier risk assessment for bees from exposure via residues in guttation fluid. EFSA PPR (2012) indicates that ETR_{acute}, $ETR_{chronic}$ and ETR_{larvae} should be calculated for potential exposure via guttation fluid. However, insufficient information is available regarding the water consumption of forager bees, in-nest bees and bee brood, and therefore it was not possible to calculate first-tier ETR values.

Screening step

As a form of screening step, a comparison of the acute toxicity of fipronil with the concentrations found in the guttation fluid is made. It is important to note that this screening step does not consider the actual consumption of water by honey bees and therefore should not be considered as a true reflection of the risk.

The acute oral LD_{50} of fipronil to honey bees is 0.00417 µg a.s./bee (Table 1). The highest residue of fipronil in guttation fluid in maize was 2.1 µg/kg, measured at growth stage BBCH 15. It can be estimated that:

- A honey bee would have to consume 1.99 g of guttation fluid to reach the acute oral LD_{50}. Assuming a relative density of 1 of the guttation fluid, this can be approximated to 1.99 ml of guttation fluid to reach the acute oral LD_{50}.

An average of 46 trips per day for water foragers was estimated by Seeley (1995). If bees carry 30 µl up to a maximum of 58 µl of water in their crop (Visscher *et al.*, 1996), they will carry a total of 1.4 – 2.7 ml of water per day (EFSA PPR, 2012).

On the basis of these calculations, it is considered that the concentrations found in the guttation fluid in maize seedlings could potentially pose a concern to honey bees if there is sufficient exposure to guttation fluid.

6.2. Risk assessment using higher tier studies

Two field studies were available investigating the occurrence of guttation fluid and honey bee activity in maize and sunflowers (see Study evaluation notes, EFSA, 2013d). Both of the studies were performed in Spain and included investigations into the occurrence of guttation fluid in the crop plants. Honey bee activity was also investigated and observations were made to estimate the number of bees on the plant and whether the honey bees were seen to take the guttation fluid. Observations for the occurrence of guttation fluid in off-crop plants were also made. A number of shortcomings in the studies were noted, such as inconsistent reporting of seed loading, and a lack of details (see Study evaluation notes, EFSA, 2013d).

The percentage of maize plants, which were observed producing guttation fluid, was a mean of 11 %, 5 % and 3 % at growth stages BBCH 10 – 19, BBCH 30 – 39 and BBCH 51 – 69, respectively. Few bees were observed on the maize plants and no bees were observed taking the guttation fluid.

The percentage of sunflower plants, which were observed producing guttation fluid, was a mean of 24 %, 20 % and 5 % at growth stages BBCH 10 – 19, BBCH 30 – 39 and BBCH 51 – 69, respectively. Few bees were observed on the sunflower plants and no bees were observed taking the guttation fluid.

The studies could potentially be considered to indicate that bees are unlikely to frequently take the guttation fluid produced by maize and sunflower plants, however, the data are considered to be too limited to be able to make general conclusions (e.g. details of alternative water sources available to the honey bees were not provided in the study report). Furthermore, it should be noted that the studies were conducted in one region of Spain only, and given that the occurrence and use of guttation fluid by honey bees are considered to be influenced by environmental and climatic conditions, extrapolation to other conditions is uncertain.

Two monitoring studies were available (Barth (2010), 2010/1062348 and Barth (2012), 2010/1062349, Study evaluation notes, EFSA, 2013d). The monitoring studies investigated the potential effect of guttation fluid produced by maize and sunflower plants grown from fipronil treated seed in commercial fields. Both studies were performed in Spain and were performed with the product 'Regent TS'. A number of shortcomings were noted with the studies (e.g. a lack of detailed information regarding alternative water sources and a lack of residue analysis; see Study evaluation notes, EFSA, 2013d).

In Barth (2010, 2010/1062348) the treatment rate of the maize seeds was 0.35 mg a.s./seed and the overall application rate was 42 g a.s./ha. With the exception of the authorised use of 'Cosmos 500FS' in the Czech Republic, the application rate tested in the maize study is considered to cover the authorised uses both in terms of the seed dressing rate and the overall application rate per hectare (see Appendix A). Bee hives were transferred to the test fields when the maize plants were at BBCH 11 – 12. Monitoring of the honey bee hives commenced immediately and included assessments of mortality, colony strength and bee brood. The occurrence and frequency of guttation fluid on the treated plants was not reported and no residue analysis of the guttation fluid was performed. It is therefore not possible to understand the level of exposure of the honey bees during the study. Statistical analysis of the bee effect data was not performed and therefore it is considered that only strong effects would be noticeable. The mortality of the honey bees in the control field was higher than that in the treatment fields. The colony strength assessments were performed up to day 61 after the start of exposure. There was no noticeable difference between the mean colony strength of the control and the mean colony strength of the treatment hives. However, it is considered that it would have been more appropriate to have analysed the colony strength results at an individual hive level. Similarly to the bee brood assessments, the study author concluded that there were no effects on bee brood, however, the analysis of the data included in the study report mainly focused on mean results rather

than individual hives. Considering the raw data presented in the study report, it is noted that there is considerable variation in the results for individual hives in both the treatment and the control groups, and therefore further analysis of the colony strength and bee brood results are considered necessary to conclude on the results of the study.

In Barth (2012, 2010/1062349) the treatment rate of the sunflower seeds was 0.2 mg a.s./seed and an overall application rate of 18 – 20 g a.s./ha. With the exception of the authorised use of 'Cosmos 500FS' in the Czech Republic, the application rate tested in the sunflower study is considered to cover the authorised uses both in terms of the seed dressing rate and the overall application rate per hectare (see Appendix A). Bee hives were transferred to the test fields when the sunflower plants were at BBCH 10 – 14. Monitoring of the honey bee hives commenced immediately and included assessments of mortality, colony strength and bee brood. The occurrence and frequency of guttation fluid on the treated plants was not reported and no residue analysis of the guttation fluid was performed. It is therefore not possible to understand the level of exposure of the honey bees during the study. Statistical analysis of the bee effect data was not performed and therefore it is considered that only strong effects would be noticeable. The mortality of the honey bees in all three of the treatment groups (different locations) was noticeably higher than that of the control during the initial part of the study (up to 12 days after the start of exposure). The study author attributed the higher mortality to movement of the hives to the treated fields. An increase in mortality due to the movement of the hives is considered to be a feasible explanation, however, an increase in mortality in the control hives was not observed. It would have been preferable to have moved the hives prior to the emergence of the sunflowers (i.e. prior to the start of potential exposure), which would have allowed a distinction to be made between the mortality due to movement of the hives and that potentially caused by exposure. Overall, it is considered that there is uncertainty as to the cause of the increased mortality in the treatment hives.

The colony strength assessments were performed up to day 46 after the start of exposure. There was no noticeable difference between the mean colony strength of the control and the mean colony strength of the treatment hives. However, it is noted that one replicate in one of the locations initially started with a lower number of bees. Furthermore, the number of bees decreased by day 12 after the start of exposure (DAE), and continued to be lower than in other hives for the remainder of the assessments. Similarly for the bee brood assessments, the study author concluded that there were no effects on bee brood, however, the analysis of the data mainly focused on mean results rather than individual hives. It is noted that in all of the hives in one of the locations the brood area covered by larvae decreased, while in the control there was an increase during the first part of the study. Furthermore, in one of the hives at that location no larvae and capped brood was observed at 32 DAE. Currently it is considered that there appears to have been a treatment-related effect on bee brood in one of the locations. Overall, further analysis of the colony strength and bee brood results is considered necessary to conclude on the results of the study.

The bee brood results in Barth (2010, 2010/1062348) and Barth (2012, 2010/1062349) were discussed during the Pesticides Peer Review Experts' Meeting 100. The lack of residue analysis and investigations concerning the frequency and occurrence of guttation fluid were considered by the experts as limitations. The experts agreed that the studies are not sufficient to exclude a risk to honey bees from residues of fipronil or its metabolites in guttation fluid. However, due to the shortcomings raised it was agreed that the potential effect on bee brood cannot be clearly attributed to the test item.

6.3. Conclusion on the risk via translocation – guttation

Exposure to honey bees via guttation fluid is not yet fully understood, however, there is evidence that, under certain conditions, honey bees may take guttation fluid. Currently there is no agreed risk assessment scheme available.

The screening assessment indicated that the magnitude of residues, measured in the guttation fluid in maize plants, are of a level that could potentially pose an acute risk to honey bees. However, the screening assessment does not consider actual consumption of water by bees and there is uncertainty

as to whether the residue value used is sufficiently worst case. Moreover, the assessment did not consider all of the metabolites which are considered relevant (see section on 'Conclusions of the evaluation').

Some higher tier data were available for maize and sunflower, which suggested that honey bees are unlikely to frequently use guttation fluid. However, the data set was considered insufficient to draw general conclusions and, as previously mentioned, the circumstances when honey bees may use guttation fluid are not fully understood.

Higher tier monitoring studies were available for maize and sunflower. However, no data were available for other crops.

Overall, the following conclusions are drawn:

Maize: The evidence from the available data does not suggest an acute effect to honey bees from exposure to guttation fluid under the conditions of the study. However, several shortcomings were noted with the available data and furthermore, extrapolation to other environmental conditions is highly uncertain. Further analysis of the long-term results is considered necessary before a conclusion can be reached. Therefore a data gap to address the risk to honey bees from the potential exposure to guttation fluid in maize is concluded (i.e. to address the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses).

Sunflower: Several shortcomings with the available data for sunflowers were noted. Furthermore, extrapolation to other environmental conditions is highly uncertain. A potential effect on bee brood was observed in one location of the available monitoring data and therefore currently a high risk to bee brood cannot be excluded. However, due to the concerns raised regarding the quality of the study, the potential effect on bee brood cannot be clearly attributed to the test item. Overall, a data gap to address the risk to honey bees from the potential exposure to guttation fluid in sunflowers is concluded (i.e. to address the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses).

Other crops: No data were available for crops other than maize and sunflowers and therefore a data gap to address the risk to honey bees from the potential exposure to guttation fluid in cauliflower, Brussels sprouts, broccoli, Chinese cabbage, Chinese broccoli, amsoy, paksoy, choi sum, komatsuna, kohlrabi, leek, onions and shallots is concluded, except crops grown and maintained in glasshouses (i.e. to address the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses).

7. Risk via translocation in succeeding crops and other plants following harvest

Exposure to residues in nectar and pollen, honeydew or guttation fluid of succeeding crops or weeds occurring in the field could represent a concern and should be further considered. Some residue studies in succeeding crops were available. No residues above the applied LOQ (0.001 mg/kg) were found in these studies, which could potentially be considered to indicate a low risk. However these studies were not considered to adequately cover all of the situations for the authorised uses (i.e. application rates, crops, pedoclimatic conditions). Furthermore, as demonstrated by the risk assessment for residues in nectar and pollen for sunflower (see section 3), the LOQ values (including 0.0005 mg/kg) may not be sufficiently low to conclude a low risk to honey bees. Furthermore, a number of persistent metabolites were identified in soil (see EFSA, 2006). It is considered necessary to ensure that all of the persistent soil metabolites are sufficiently addressed. Therefore a data gap was concluded for further assessment of the risk to honey bees from residues in nectar and pollen, honeydew and guttation fluid of succeeding crops or weeds occurring in the field (i.e. to address the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses), ensuring that all persistent soil metabolites (see Appendix D) are also sufficiently

addressed for all the uses evaluated, except for crops grown and maintained in permanent glasshouses and where the growing media is not spread in the agricultural environment.

8. Monitoring data

Limited monitoring data were available for fipronil. Residue analysis on samples of bees, beebread and plant material was carried out in the framework of the MELISSA project which also included fipronil. MELISSA ("Investigations in the incidence of bee losses in corn and oilseed rape growing areas of Austria and possible correlations with bee diseases and the use of insecticidal plant protection products") (Austria, 2012) was a monitoring project conducted in Austria during 2009, 2010 and 2011. The results of the MELISSA project provided evidence that regional clustered bee damage had occurred in the years 2009 – 2011, which was frequently associated with the use of maize and oilseed pumpkin seeds coated with insecticides, as proved by residue analysis. Fipronil was detected in 14 % of the bee samples and metabolite MB 46136 (referred to as 'sulfone compound' in MELISSA) in 9 % of the bee samples, while they were never detected in plants or bee bread. Bee loss was correlated to local factors, such as small-scale structured agriculture, contributing to the increase in exposure of bees. Equally, the presence of disease and combined stresses could have contributed to or caused the colony damage.

Residue analysis in pollen loads of fipronil and its metabolites MB 46513 (referred to as 'desulfinyl compound' in the paper below) and MB 46136 (referred to as 'sulfone compound' in the paper below) was conducted in the framework of a 3-year field survey in France. Several published papers were available on this field survey (Chauzat *et al*., 2006, 2009, 2011). In these papers fipronil was reported as one of the most frequent residue found in bee pollen loads (12.4 % of the sample, 185 samples), showing a peak in March and April, concurring with sunflower sowing. Although fipronil was detected (above the LOD, mean in positive samples: 1.2 µg/kg), it was below the limit of quantification (2 µg/kg). The metabolites MB 46513 and MB 46136 were detected above the LOQ (maximum residue was 1.5 µg/kg and 3.7 µg/kg, respectively, mean residue was 1.7 µg/kg and 1.0 µg/kg, respectively). It was noted that pollen palynological analysis was not carried out. Therefore it is not possible to link these results with a specific crop. In addition, in 2003, in France, there were several authorised uses of products containing fipronil in agriculture as seed treatments but also as soil treatments (spray and granules). The main crops were cereals, maize, sunflower and sugar beet. There were also several non-regulated biocide uses. Therefore it is also difficult to link these results with the seed treatment uses. Residue analyses of fipronil and its metabolites MB 46136 and MB 46513 in honey and honey bee samples were also reported. In honey, fipronil and its metabolites were never detected, while in honey bees samples they were detected in 9.1 % of the samples; mean concentration of residues in positive samples was: 0.5 (fipronil), 1.2 (MB 46513) and 0.4 (MB 46136) µg/kg. In Chauzat *et al*, 2009 and 2011 also honey bee colony health was studied in relation to pesticide residues found in the colonies. No significant relationship was found between the presence of pesticide residues and the abundance of brood and adults, nor between colony mortality and pesticide residues.

Pesticide residue analysis in stored pollen and potential effects on honey bee health were investigated in Spain by Bernal *et al.*, (2010). The authors reported that fipronil was detected in 3.7 % of all the spring samples but never in the autumn samples. The palynological analysis showed that sunflower pollen was detected in 10.4 % of the samples. In a following study, focused on sunflower areas and fipronil (Bernal *et al.*, 2011), the authors failed to detect fipronil and its metabolites (i.e. < LOD of 0.2 µg/kg).

A summary of a 5-year monitoring study was reported in the Hungarian Veterinary Journal (Fazekas *et al.*, 2012). Suspicious bee incidence cases were investigated by the relevant authorities (National Food Chain Safety Office, Central Veterinary Institute) between 2007 and 2011. 222 honey bee samples and 129 plant samples (assumed to be linked with the bee mortality) were sent for veterinary diagnostic laboratory examination. The presence of contagious diseases (nosemosis, varroasis and *Malpighamoeba mellificae*) was excluded, but 12 different pesticides (most frequently organophosphates, pyrethroids and fipronil) were detected in 151 honey bee samples. In 64 cases the plant samples contained the same pesticide(s) as the honey bees of the same case, thus confirming the

link between the application of the pesticide(s) to the crop and the likely bee poisoning. It was concluded by the authors that the most severe impact on the bee colonies was observed in the fipronil cases. Fipronil was detected in 16 out of the 151 positive bee samples and in 12 out of the 64 positive plant samples. It is noted that the spray uses of fipronil were banned in Hungary in 2008 and the majority of the cases were registered after the ban. The cases from 2009 were highlighted because they caused very serious effects; mortality of honey bees was observed over a long period in 10 apiaries in North-East of Hungary. Almost 1000 bee colonies were affected, including effects on brood. Honey samples also included residues of fipronil. The authorities detected that products containing fipronil, or fipronil and chlorpyrifos were misused in flowering orchards (apple and pear). Fipronil was not authorised for orchard uses even before 2009 (not even for uses out of the flowering periods).

Other sources of information, reporting monitoring activities in relation to honey bee health, was also considered. For example the paper from Genersch, *et al*., (2010) on the German bee monitoring project aimed at understanding the periodically high winter losses of honey bees; the APENET project, an Italian monitoring network established in 2009 - 2011 (APENET report, 2011, and EFSA 2012); the reports on bee poisoning incidents in spring 2011 in the region of Pomurje (Slovenia, 2012); and the UK Wildlife Incident Investigation Scheme (WIIS), which relies on members of the public/farmers reporting suspected wildlife poisoning. According to the investigations reported, between 1997 and 2012 (CRD, 2013 and Environmental Panel of the Advisory Committee on Pesticides, 1998 - 2007), there was a single case of fipronil detected in dead bee samples in 2010; the source of fipronil was unknown. Overall, these project can be considered not relevant for fipronil because either it was not investigated or very rarely reported.

8.1. Overall conclusion on the monitoring data

During the Pesticides Peer Review Experts' Meeting 97 (November 2012) to discuss the neonicotinoid active substances (clothianidin, thiamethoxam and imidacloprid), the experts considered the potential use of monitoring data for risk assessment. It was agreed that it can be difficult to use monitoring data directly in risk assessment due to the fact that there are many influential parameters in the monitoring data that cannot be fully understood (pesticide exposure, climatic conditions, presence of disease, farming practices, etc.). Furthermore, it is difficult to link exposure and observed effects in monitoring data (i.e. causality). It was also noted that monitoring data may not provide a complete picture as, in some cases, not all parameters are investigated (e.g. use of veterinary medicines). It was also noted that the monitoring data are only relevant to the specific Member State (and to the GAPs approved in that Member State) and not to all authorised uses, and environmental and agronomic conditions in the EU. Overall, it was concluded that monitoring data are of limited use for risk assessment but may be useful to provide feedback for risk managers to consider prevention measures.

9. List of data gaps identified during the assessment

- Information to address the exposure and hence the risk to bees from plant and soil metabolites, except the soil photolysis metabolites (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses), relevant for **all the uses** evaluated, **except crops grown and maintained in permanent glasshouses** and where the **growing media** is **not spread** in the agricultural environment (see section on 'Conclusions of the evaluation').

- Information to address the risk to pollinators (other than honey bees), relevant for **all the uses** evaluated, **except crops grown and maintained in permanent glasshouses** and where **pollinators** are **not used for pollination** (see section on 'Conclusions of the evaluation').

- Information to address the risk (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses) to honey bees for situations where bees forage on vegetation exposed to dust drift emitted during the drilling procedure, relevant for **all the uses** evaluated **except for crops sown in glasshouse** (see section 2.5).

- Further information to address the risk following the ingestion of contaminated nectar and/or pollen (i.e. the acute risk and the long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses) in **sunflower** and **maize**. The data gap, identified in the previous EFSA Conclusion (EFSA 2006), to address the contamination of the control residue samples in the bee tunnel study in Spain (BASF DocID 2005/1006522; Schur A. 2005 and BASF DocID 2005/1006523; Schur A. 2005) was maintained (see section 3.6).

- Further information to address the risk to honey bees foraging on insect honeydew (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses), relevant for **all the uses** evaluated **except crops grown and maintained in glasshouses** (see section 4).

- Further information to address the risk to honey bees from the potential exposure to guttation fluid (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses), relevant for **all the uses** evaluated **except crops grown and maintained in glasshouses** (see section 6.3).

- Information to address the risk to honey bees from residues in nectar and pollen, honeydew and guttation fluid of succeeding crops or weeds occurring in the field, ensuring that all persistent soil metabolites (RPA 200766, MB 46136 and MB 45950) are also sufficiently addressed (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood and bee behaviour, including an assessment of sublethal doses), relevant for **all the uses** evaluated, **except crops grown and maintained in permanent glasshouses** and where the **growing media** is **not spread** in the agricultural environment (see section 7)**.**

10. Particular conditions proposed to be taken into account to manage the risk(s) identified

- A low risk from exposure via residues **in nectar and/or pollen** can be concluded **for all uses on vegetables** (cauliflower, Brussels sprouts, broccoli, Chinese cabbage, Chinese broccoli, amsoy, paksoy, choi sum, komatsuna, kohlrabi, leek, onions and shallot), provided that these crops would not be allowed to flower (e.g. for seed-production purposes), outdoor.

11. Concerns

11.1. Issues that could not be finalised

Several issues that could not be finalised were identified in relation to the exposure of honey bees via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation fluid. In addition, the risk from residues in insect honeydew, the risk from exposure to residues in succeeding crops or weeds, the risk from plant and soil metabolites (except soil photolysis metabolites), and the risk to pollinators other than honey bees could not be finalised on the basis of the available data.

The assessments are considered not finalised where there were no data, or insufficient data available to reach a conclusion, or where there are no agreed risk assessment schemes available. The issues that could not be finalised are marked with an 'X' in the overview table in section 11.3.

11.2. Critical areas of concern

A high acute risk to honey bees was identified from exposure via dust drift for the authorised uses in maize.

The risks identified are marked with an 'R' in the overview table in section 11.3. Risks have been identified where either a 1st tier 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.

11.3. Overview of the concerns identified for the authorised uses considered

X **Assessment not finalised** – where there were no data, or insufficient data available to reach a conclusion / where there are no agreed risk assessment schemes available.

R **Risk identified** – where either a 1st tier assessment indicated a high risk (not including the screening step assessment for exposure via dust and guttation) or higher tier study indicated a high risk.

Crop/Situation	Product Name	Member States	'Maximum application rate' g a.s./ha	Acute risk to honey bees			Chronic risk to honey bees			Risk to honey bees from sublethal effects / effects on larvae			Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops	Risk from plant and soil metabolites
				Dust	Residues in nectar and/or pollen	Residues in guttation fluid	Dust	Residues in nectar and/or pollen	Residues in guttation fluid	Dust	Residues in nectar and/or pollen	Residues in guttation fluid				
Cauliflower, Brussels sprouts, Broccoli, Chinese cabbage, Chinese broccoli, Amsoy, Paksoy, Choi sum, Komatsuna, Kohlrabi	Mundial (glasshouse)	NL	20			X[1]			X[1]			X[1]	X[1]	X[1]	X[2]	X[3]
Maize (Corn)	Cosmos 500FS	BG	35	R	X	X	X	X	X	X	X	X	X	X	X	X
	Cosmos 500FS	CZ	44	R	X	X	X	X	X	X	X	X	X	X	X	X
	Regent 500FS	ES	35	R	X	X	X	X	X	X	X	X	X	X	X	X
	Cosmos 500FS	HU	26.25	R	X	X	X	X	X	X	X	X	X	X	X	X
	Cosmos 500FS	SK	35	R	X	X	X	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member States	'Maximum application rate' g a.s./ha	Acute risk to honey bees			Chronic risk to honey bees			Risk to honey bees from sublethal effects / effects on larvae			Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops	Risk from plant and soil metabolites
				Dust	Residues in nectar and/or pollen	Residues in guttation fluid	Dust	Residues in nectar and/or pollen	Residues in guttation fluid	Dust	Residues in nectar and/or pollen	Residues in guttation fluid				
Leek	Mundial	BE	72	X		X	X		X	X		X	X	X	X	X
	Mundial (glasshouse)	NL	50			X[1]			X[1]			X[1]	X[1]	X[1]	X[2]	X[3]
	Mundial (field)	NL	72	X		X	X		X	X		X	X	X	X	X
Onions, shallots	Mundial	BE	110	X		X	X		X	X		X	X	X	X	X
	Mundial (field)	NL	110	X		X	X		X	X		X	X	X	X	X
Sunflower	Cosmos 500FS	BG	18	X	X	X	X	X	X	X	X	X	X	X	X	X
	Cosmos 500FS	CZ	14	X	X	X	X	X	X	X	X	X	X	X	X	X
	Regent 500FS	ES	18	X	X	X	X	X	X	X	X	X	X	X	X	X
	Cosmos 500FS	HU	10	X	X	X	X	X	X	X	X	X	X	X	X	X
	Cosmos 500FS	SK	18	X	X	X	X	X	X	X	X	X	X	X	X	X

Table compiled on the basis of Appendix A

[1] Only relevant for situations where seedlings grown from treated seeds are transferred to the field.

[2] Assumes exposure to soil either via seedlings being transferred to the field or disposal of spent growing media.

[3] Relevant for situations where seedlings grown from treated seeds are transferred to the field or there is exposure to soil either via seedlings being transferred to the field or disposal of spent growing media

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APPENDICES

APPENDIX A – FIPRONIL: SUMMARY OF AUTHORISED USES IN THE EU

Crop/Situation	Product Name	Member States	Method of application	Application rate per treatment			
				'Minimum application rate' g a.s./ha	'Maximum application rate' g a.s./ha	Seed dressing rate (quantity of a.s./seed)	Seed drilling rate (quantity of seeds/ha)
Cauliflower, Brussels sprouts, Broccoli, Chinese cabbage, Chinese broccoli, Amsoy, Paksoy, Choi sum, Komatsuna, Kohlrabi	Mundial	NL	Slurry seed dressing	5	20	0.125 mg	100 000 - 160 000 plants/ha greenhouse seeding, transplanted to the field (at BBCH 12/14, in April-July).
Corn, Maize	Cosmos 500FS	BG	Slurry seed dressing	25	35	0.35 mg	70 000 - 100 000
	Cosmos 500FS	CZ	Slurry seed dressing	26	44	1.25 kg a.s./1000 kg	70 000 - 100 000
	Regent 500FS	ES	Slurry seed dressing	25	35	0.35 mg	70 000 - 100 000
	Cosmos 500FS	HU	Slurry seed dressing	17.5	26.25	0.35 mg	50 000 - 75 000
	Cosmos 500FS	SK	Slurry seed dressing	24	35	0.35 mg	70 000 - 100 000
Leek	Mundial	BE	Slurry seed dressing	50	72	0.1 mg	500 000 - 720 000
	Mundial	NL	Slurry seed dressing	50	50	0.2 mg	12 000 000 seeds/ha in the greenhouse; 250 000 plants/ha in the field
	Mundial	NL	Slurry seed dressing	72	72	0.2 mg	360 000 seeds/ha (with 70 % emergence, i.e. 250 000 plants/ha)

Crop/Situation	Product Name	Member States	Method of application	Application rate per treatment			
				'Minimum application rate' g a.s./ha	'Maximum application rate' g a.s./ha	Seed dressing rate (quantity of a.s./seed)	Seed drilling rate (quantity of seeds/ha)
Onions, shallots	Mundial	BE	Slurry seed dressing	100	110	0.1 mg	1 000 000 - 1 100 000
	Mundial	NL	Slurry seed dressing	100	110	0.1 mg	1 000 000 - 1 100 000
Sunflower	Cosmos 500FS	BG	Slurry seed dressing	9	18	0.2 mg	45 000 - 90 000
	Cosmos 500FS	CZ	Slurry seed dressing	5	14	1.25 kg a.s./1000 kg	50 000 - 90 000
	Regent 500FS	ES	Slurry seed dressing	9	18	0.2 mg	45 000 - 90 000
	Cosmos 500FS	HU	Slurry seed dressing	10	10	0.2 mg	50 000
	Cosmos 500FS	SK	Slurry seed dressing	9	18	0.2 mg	45 000 - 90 000

Table compiled based on feedback provided by the applicant (BASF) and Member States for the request of EFSA in November 2012. (Note: not all the 27 Member States provided feedback).

APPENDIX B – FIPRONIL: NECTAR AND POLLEN RESIDUE DATA SET (BASED ON THE APPLICANT'S DOSSIERS)

Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
fipronil	Regent TS	na	maize	FR	pollen	0.00195	Kerl W.	2005	2005/1006469
MB 46136	Regent TS	na	maize	FR	pollen	< 0.00050	Kerl W.	2005	2005/1006469
MB 45950	Regent TS	na	maize	FR	pollen	< 0.00050	Kerl W.	2005	2005/1006469
MB 46513	Regent TS	na	maize	FR	pollen	< 0.00050	Kerl W.	2005	2005/1006469
RPA 200766	Regent TS	na	maize	FR	pollen	< 0.00050	Kerl W.	2005	2005/1006469
fipronil	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	DE,FR (North)	pollen	< 0.00050	Schur	2005	2005/1006470
MB 46136	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	DE,FR (North)	pollen	< 0.00050	Schur	2005	2005/1006470
MB 45950	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	DE,FR (North)	pollen	< 0.00050	Schur	2005	2005/1006470
MB 46513	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	DE,FR (North)	pollen	< 0.00050	Schur	2005	2005/1006470
RPA 200766	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	DE,FR (North)	pollen	< 0.00050	Schur	2005	2005/1006470
fipronil	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	FR (South), ES	pollen	0.0105**	Schur	2005	2005/1006470
MB 46136	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	FR (South), ES	pollen	< 0.00050	Schur	2005	2005/1006470
MB 45950	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	FR (South), ES	pollen	< 0.00050	Schur	2005	2005/1006470
MB 46513	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	FR (South), ES	pollen	< 0.00050	Schur	2005	2005/1006470
RPA 200766	BAS 350 23 I (fipronil 500 g/L)	50.21 g a.s./ha	maize	FR (South), ES	pollen	< 0.00050	Schur	2005	2005/1006470
fipronil	Regent TS		maize	FR (midi-pyrenees and rhone-alpes)	pollen	**0.0064*** **	Kerl W.	2005	2005/1006536 and 2005/1004979
MB 46136	Regent TS		maize	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Kerl W.	2005	2005/1006536 and 2005/1004979
MB 45950	Regent TS		maize	FR (midi-	pollen	< 0.00050	Kerl W.	2005	2005/1006536 and

Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
				pyrenees and rhone-alpes)					2005/1004979
MB 46513	Regent TS		maize	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Kerl W.	2005	2005/1006536 and 2005/1004979
RPA 200766	Regent TS		maize	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Kerl W.	2005	2005/1006536 and 2005/1004979
fipronil	Regent 500 TS	43.48 g a.s/ha	maize	SW	pollen	< 0.00050	Jeker	2009	2008/1014946
MB 46136	Regent 500 TS	43.48 g a.s/ha	maize	SW	pollen	< 0.00050	Jeker	2009	2008/1014946
MB 45950	Regent 500 TS	43.48 g a.s/ha	maize	SW	pollen	< 0.00050	Jeker	2009	2008/1014946
MB 46513	Regent 500 TS	43.48 g a.s/ha	maize	SW	pollen	< 0.00050	Jeker	2009	2008/1014946
RPA 200766	Regent 500 TS	43.48 g a.s/ha	maize	SW	pollen	< 0.00050	Jeker	2009	2008/1014946
fipronil	na	na	sunflower	FR	pollen	< 0.0010	Sophie AYOUB / Jean-Luc KIEKEN	2001	2001/1024450
MB 46136	na	na	sunflower	FR	pollen	< 0.0010	Sophie AYOUB / Jean-Luc KIEKEN	2001	2001/1024450
MB 45950	na	na	sunflower	FR	pollen	< 0.0010	Sophie AYOUB / Jean-Luc KIEKEN	2001	2001/1024450
MB 46513	na	na	sunflower	FR	pollen	< 0.0010	Sophie AYOUB / Jean-Luc KIEKEN	2001	2001/1024450
RPA 200766	na	na	sunflower	FR	pollen	< 0.0010	Sophie AYOUB / Jean-Luc KIEKEN	2001	2001/1024450
fipronil	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017628
MB 46136	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017628
MB 45950	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017628
MB 46513	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017628

Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
RPA 200766	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017628
fipronil	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017629
MB 46136	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017629
MB 45950	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017629
MB 46513	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017629
RPA 200766	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	2002-1017629
fipronil	na	na	sunflower	FR/Chazay	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027432
MB 46136	na	na	sunflower	FR/Chazay	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027432*
MB 45950	na	na	sunflower	FR/Chazay	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027432*
MB 46513	na	na	sunflower	FR/Chazay	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027432*
RPA 200766	na	na	sunflower	FR/Chazay	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027432*
fipronil	na	na	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027438*
MB 46136	na	na	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc	2002	C027438*

Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
							KIEKEN		
MB 45950	na	na	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027438*
MB 46513	na	na	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027438*
RPA 200766	na	na	sunflower	FR/Toulouse	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027438*
fipronil	na	na	sunflower	FR/Reims	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027959*
MB 46136	na	na	sunflower	FR/Reims	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027959*
MB 45950	na	na	sunflower	FR/Reims	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027959*
MB 46513	na	na	sunflower	FR/Reims	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027959*
RPA 200766	na	na	sunflower	FR/Reims	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027959*
fipronil	na	na	sunflower	FR/Amiens	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027961*
MB 46136	na	na	sunflower	FR/Amiens	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027961*
MB 45950	na	na	sunflower	FR/Amiens	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027961*
MB 46513	na	na	sunflower	FR/Amiens	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027961*

Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
RPA 200766	na	na	sunflower	FR/Amiens	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027961*
fipronil	na	na	sunflower	na	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027963
MB 46136	na	na	sunflower	na	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027963
MB 45950	na	na	sunflower	na	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027963
MB 46513	na	na	sunflower	na	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027963
RPA 200766	na	na	sunflower	na	nectar	< 0.0010	Sophie AYOUB/Jean-Luc KIEKEN	2002	C027963
fipronil	Regent TS	na	sunflower	FR	nectar	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
MB 46136	Regent TS	na	sunflower	FR	nectar	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
MB 45950	Regent TS	na	sunflower	FR	nectar	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
MB 46513	Regent TS	na	sunflower	FR	nectar	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
RPA 200766	Regent TS	na	sunflower	FR	nectar	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
fipronil	Regent 500 TS	30 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170012
MB 46136	Regent 500 TS	30 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170012
MB 45950	Regent 500 TS	30 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170012
MB 46513	Regent 500 TS	30 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170012
RPA 200766	Regent 500 TS	30 g a.s/ha	sunflower	SP	nectar	0.0033	Bocksch	2009	2008/10170012
fipronil	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170011
MB 46136	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170011
MB 45950	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170011
MB 46513	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170011

Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
RPA 200766	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	nectar	< 0.00050	Bocksch	2009	2008/10170011
fipronil	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	pollen	< 0.0010	Salvi M.	2002	2002/1017630
MB 46136	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	pollen	< 0.0010	Salvi M.	2002	2002/1017630
MB 45950	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	pollen	< 0.0010	Salvi M.	2002	2002/1017630
MB 46513	REGENT TS (500 g fipronil/L)	1 L/100 kg	sunflower	FR/Lion	pollen	< 0.0010	Salvi M.	2002	2002/1017630
fipronil	na	na	sunflower	FR/Reims	pollen	< 0.0010	Salvi M.	2002	C026119*
MB 46136	na	na	sunflower	FR/Reims	pollen	< 0.0010	Salvi M.	2002	C026119*
MB 45950	na	na	sunflower	FR/Reims	pollen	< 0.0010	Salvi M.	2002	C026119*
MB 46513	na	na	sunflower	FR/Reims	pollen	< 0.0010	Salvi M.	2002	C026119*
fipronil	na	na	sunflower	FR/Amiens	pollen	< 0.0010	Salvi M.	2002	C026120*
MB 46136	na	na	sunflower	FR/Amiens	pollen	< 0.0010	Salvi M.	2002	C026120*
MB 45950	na	na	sunflower	FR/Amiens	pollen	< 0.0010	Salvi M.	2002	C026120*
MB 46513	na	na	sunflower	FR/Amiens	pollen	< 0.0010	Salvi M.	2002	C026120*
fipronil	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Salvi M.	2002	C027966*
MB 46136	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Salvi M.	2002	C027966*
MB 45950	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Salvi M.	2002	C027966*
MB 46513	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Salvi M.	2002	C027966*
fipronil	na	na	sunflower	FR/Chazay	pollen	< 0.0010	Sole C.	2002	C028180*
MB 46136	na	na	sunflower	FR/Chazay	pollen	< 0.0010	Sole C.	2002	C028180*
MB 45950	na	na	sunflower	FR/Chazay	pollen	< 0.0010	Sole C.	2002	C028180*
MB 46513	na	na	sunflower	FR/Chazay	pollen	< 0.0010	Sole C.	2002	C028180*
fipronil	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Sole C.	2002	C028182*
MB 46136	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Sole C.	2002	C028182*
MB 45950	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Sole C.	2002	C028182*

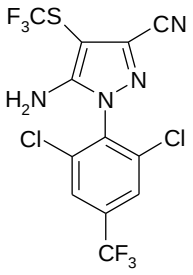
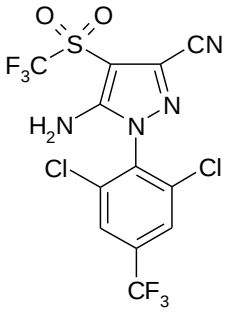
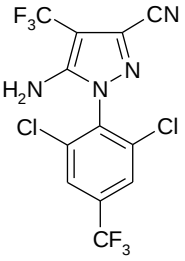
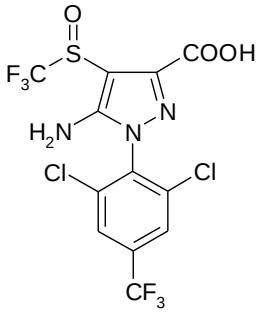
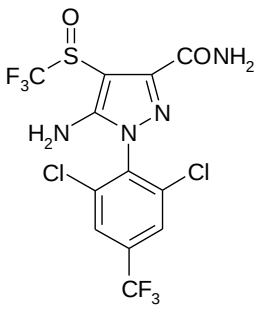
Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
MB 46513	na	na	sunflower	FR/Toulouse	pollen	< 0.0010	Sole C.	2002	C028182*
fipronil	REGENT TS	na	sunflower	na	pollen	< 0.0010	Benazeraf L.	2004	2004/1015950
MB 46136	REGENT TS	na	sunflower	na	pollen	< 0.0010	Benazeraf L.	2004	2004/1015950
fipronil	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 46136	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 45950	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 46513	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
RPA 200766	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
fipronil	Regent TS	500 g/L, 18.24-28.48 g a.s./ha (derived)	sunflower	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Decourtye, Kerl	2005	2005/1006536 and 2005/1004979
MB 46136	Regent TS	500 g/L, 18.24-28.48 g a.s./ha (derived)	sunflower	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Decourtye, Kerl	2005	2005/1006536 and 2005/1004979
MB 45950	Regent TS	500 g/L, 18.24-28.48 g a.s./ha (derived)	sunflower	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Decourtye, Kerl	2005	2005/1006536 and 2005/1004979
MB 46513	Regent TS	500 g/L, 18.24-28.48 g a.s./ha (derived)	sunflower	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Decourtye, Kerl	2005	2005/1006536 and 2005/1004979
RPA 200766	Regent TS	500 g/L, 18.24-28.48 g a.s./ha (derived)	sunflower	FR (midi-pyrenees and rhone-alpes)	pollen	< 0.00050	Decourtye, Kerl	2005	2005/1006536 and 2005/1004979
fipronil	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 46136	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 45950	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 46513	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471

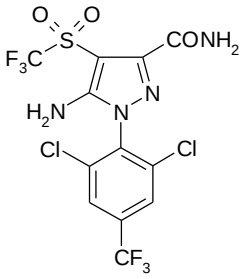
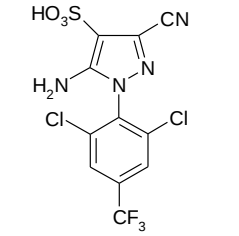
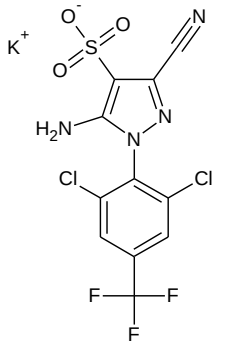
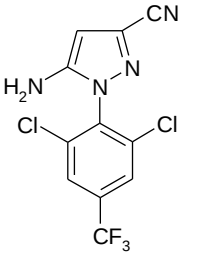
Substance	Formulation	Dose g a.s/ha	Crop	Site	Matrix	Residue (mg a.s/kg) max	Authors	Date	Study ID
RPA 200766	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
fipronil	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170011
MB 46136	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170011
MB 45950	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170011
MB 46513	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170011
RPA 200766	Regent 500 TS	29.34 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170011
fipronil	Regent 500 TS	30 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170012
MB 46136	Regent 500 TS	30 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170012
MB 45950	Regent 500 TS	30 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170012
MB 46513	Regent 500 TS	30 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170012
RPA 200766	Regent 500 TS	30 g a.s/ha	sunflower	SP	pollen	< 0.00050	Bocksch	2009	2008/10170012
fipronil	Regent TS	na	sunflower	FR	pollen	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
MB 46136	Regent TS	na	sunflower	FR	pollen	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
MB 45950	Regent TS	na	sunflower	FR	pollen	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
MB 46513	Regent TS	na	sunflower	FR	pollen	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
RPA 200766	Regent TS	na	sunflower	FR	pollen	< 0.00050	Decourtye, Tisseur	2005	2005-1006529
fipronil	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 46136	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 45950	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
MB 46513	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471
RPA 200766	BAS 350 23 I (fipronil 500 g/L)	20	sunflower	FR	pollen	< 0.00050	Schur	2005	2005/1006471

na: not applicable
* sunflower was the following crop. In the treated plots cereals were treated with TEXAS 50 g a.s./100 kg
**value not used for risk assessment because not reliable due to control contamination
***Value in **bold** used for risk assessment for maize crop.

NOTES:
1) For sunflower the LOQ of 0.0005 mg/kg was used for risk assessment
2) Residue data from semi-filed studies conducted in Spain in 2004 (Shur A. 2005, BASF DocID 2005/1006522, BASF DocID 2005/1006523) were not reported because these were considered not reliable due to control contamination.

APPENDIX C– USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula
MB 45950	5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-trifluoromethylthio-1-pyrazole-3-carbonitrile	
MB 46136	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1*H*-pyrazole-3-carbonitrile	
MB 46513	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(trifluoromethyl)-1*H*-pyrazole-3-carbonitrile	
RPA 200761	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carboxylic acid	
RPA 200766	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carboxamide	

Code/Trivial name	Chemical name*	Structural formula
RPA 105320	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1*H*-pyrazole-3-carboxamide	
RPA 104615	5-amino-3-cyano-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1*H*-pyrazole-4-sulfonic acid potassium 5-amino-3-cyano-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1*H*-pyrazole-4-sulfonate	 * 
MB 45897	5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1*H*-pyrazole-3-carbonitrile	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

APPENDIX D – FIPRONIL: SUMMARY OF SOIL AND PLANT METABOLITES

Soil

Compound (name and/or code)	Persistence
fipronil	Moderate to high persistent ($DT_{50\ lab\ aerobic}$ = 32 - 346 day)
RPA 200766	High persistent ($DT_{50\ lab\ aerobic}$ = 160 - 213.6 day)
MB 46136	High persistent ($DT_{50\ lab\ aerobic}$ = 265 - 422 day)
MB 45950	High persistent ($DT_{50\ lab\ aerobic}$ = 128 - 337 day)
MB 46513	Medium to high persistent ($DT_{50\ lab\ aerobic}$ = 66 - 147 day) Soil photolysis metabolite, not formed in soil from seed treatment and incorporated uses
RPA 104615	Soil photolysis metabolite, not formed in soil from seed treatment and incorporated uses

Source: EFSA, 2006

Plants

Compound (name and/or code)	Crop species, plant organ and levels measured (Note: % indicated are of total radioactive residues (TRR) in the plant parts sampled; less than 5 % of the radioactivity applied to seeds or soil (as phenyl radiolabelled fipronil) was taken up into the aerial plant organs at the time when the samples were taken.)
fipronil	12 - 72 % TRR in sunflower, cotton, maize and wheat
RPA 200766	3 – 64 % TRR in sunflower, maize fodder, cotton foliage and sugar beet leaves,
RPA 200761	7.7 – 60 % TRR in maize forage, wheat grain, sunflower seeds and cotton foliage
RPA 105320	18 % TRR in sugar beet leaves
MB 46136	1 – 31 % TRR in sunflower and sunflower seeds, maize fodder, cotton foliage and sugar beet leaves
MB 45950	0.5 - 3.6 % TRR in sunflower leaves, total sunflower aerial parts, maize fodder and sugar beet leaves
RPA 104615	6.6 % TRR in sunflower seeds
MB 46513	1.2 % TRR in sunflower leaves and stalks

Source: Vol. 3 B7 DAR (France, 2004) and Final Addendum to the DAR (part 2) (France, 2006)

ABBREVIATIONS

µg	microgram
a.s.	active substance
AF	assessment factor
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
COM	European Commission
d	day
DAE	day after exposure
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EAC	environmentally acceptable concentration
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
EEC	European Economic Community
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETR	exposure to toxicity ratio
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FR	France
g	gram
GAP	good agricultural practice
GLP	good laboratory practice
GM	geometric mean
GS	growth stage
h	hour(s)
ha	hectare
HQ	hazard quotient
L	litre
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOEC	lowest observable effect concentration
LOER	lowest observable effect rate
LOD	limit of detection
LOQ	limit of quantification
m	metre
MAF	multiple application factor
mg	milligram
ml	millilitre
mm	millimetre
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
NOER	no observed effect rate
OM	organic matter content
Pa	Pascal
PER	proboscis extension response
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RFID	radiofrequency identification
RI	residue intake
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SP	Spain
SSD	species sensitivity distribution
SW	Sweden
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TLV	threshold limit value
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WHO	World Health Organisation
wk	week
yr	year