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CONCLUSION ON PESTICIDE PEER REVIEW

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

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ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment of neonicotinoids, including imidacloprid, as regards the risk to bees. In this context the conclusions of EFSA concerning the risk assessment for bees for the active substance imidacloprid 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 uses of imidacloprid applied as a seed treatment or granules on a variety of crops currently authorised in Europe. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data as well as the available EU evaluations and monitoring data, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

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KEY WORDS

Imidacloprid, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/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 use as a seed treatment 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 April 2012 the European Commission requested the EFSA to provide conclusions as regards the risk of neonicotinoid active substances 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. Following discussions at the Standing Committee on the Food Chain and Animal Health (SCFCAH) in June / July 2012 and taking into account the outcome of the EFSA statement on the findings in recent studies investigating sublethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe (EFSA Journal 2012;10(6):2752), the EFSA received an updated request from the European Commission to prioritise the review of 3 neonicotinoid substances, including imidacloprid, and to perform an evaluation of the currently authorised uses of these substances as seed treatments and granules.

The conclusions laid down in this report were reached on the basis of the evaluation of the studies submitted for the approval of the active substance at EU level and for the authorisation of plant protection products containing imidacloprid at Member State level, for the uses as seed treatments or granules applied on a variety of crops in Europe. In addition, 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), some relevant literature data as well as monitoring data available at national level were also considered 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 as seed treatments and granules. Furthermore, the risk assessment for pollinators other than honey bees, the risk assessment following exposure to insect honey dew and the risk assessment from exposure to succeeding crops could not be finalized 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

Imidacloprid was included in Annex I to Directive 91/414/EEC[3] on 1 August 2009 by Commission Directive 2008/116/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 29 May 2008 as set out in the EFSA Scientific Report (2008) 148 (EFSA, 2008).

The specific provisions of the approval were amended by Commission Directive 2010/21/EU8, to permit use as a seed treatment 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, 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 25 April 2012, the European Commission requested the EFSA to provide conclusions as regards the risk of neonicotinoid active substances 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.

Following discussions at the Standing Committee on the Food Chain and Animal Health (SCFCAH) in June / July 2012, and taking into account the outcome of the EFSA statement on the findings in recent studies investigating sublethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe (EFSA, 2012b), the EFSA received an updated request from the European Commission on 30 July 2012. With this new mandate, EFSA was asked to prioritise the review of 3 neonicotinoid substances, including imidacloprid, and to perform an evaluation of the authorised uses as seed treatments and granules, focusing on:

- dust from seeds and granules;
- residues in nectar and pollen and sublethal effects on bees and bee colonies survival;
- guttation.

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 October 2012. The draft conclusions drawn by EFSA, together with the points that required further consideration in the assessment, as well

[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 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86-91.

[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.

as the specific issues raised by Member States following the consultation were discussed at the Pesticides Peer Review Experts' Meeting 97 on ecotoxicology in November 2012. 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 December 2012.

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, with regard to the uses of imidacloprid authorised as seed treatments or granules on a variety of crops in Europe. In addition to the available EU evaluations including EFSA Conclusions, the EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (EFSA, 2012a) was also taken into account. Furthermore, some relevant literature data as well as monitoring data made available by Member States during the peer review were also considered 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, 2012d) 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.

[9] As no Draft Assessment Report was available in the context of this peer review, the studies and available data submitted by the applicant(s) 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

The risk assessment was performed taking into consideration the recommendations in EFSA 2012a.

The experts at the Pesticides Peer Review Experts' Meeting 97 (November 2012) expressed concern over the scope of the risk assessments performed. Some experts highlighted that their Member State had made considerable progress in improving the quality of seed treatment processes or have specific agronomic practices in place which could reduce the potential risk to pollinators. The Member State experts were concerned that, due to consideration of all authorised uses in the EU, it was not possible to adequately account for these specific Member State practices and authorised GAPs. It was also noted that some of the studies were conducted specifically to address a concern raised by the Member State during national registration; therefore, the data were not designed or intended to cover all of the authorised uses in the EU. Although the concerns raised by the Member States are acknowledged, it was noted that specific information on Member State agronomic practices (e.g. seed treatment quality criteria, drilling machine criteria) was not available and therefore could not be accounted for in the risk assessments.

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 assessment, such as assessments for dust drift. The recently published study on bumble bees (Gill, 2012) was considered during the Pesticides Peer Review Experts' Meeting 97. The research considered the combined effects of two insecticides (imidacloprid and lambda-cyhalothrin). It was noted that there is an apparent effect on the brood development from exposure to imidacloprid, which was possibly caused indirectly by an adverse effect on the foragers at a level of 10 ppb. It was noted that the exposure regime in the study may not be realistic and therefore provides limited use for risk assessment (the bees were offered feeders containing sugar syrup spiked with imidacloprid and/or had to walk over a filter paper which was contaminated with lambda-cyhalothrin). Overall, the risk to pollinators other than honey bees should be further considered. Therefore a data gap was concluded for further information to address the risk to pollinators (other than honey bees).

Exposure to residues in succeeding crops in nectar and pollen or guttation fluid could represent a concern and should be further considered. A few residue studies in succeeding crops were available and confirmed that this route of exposure is possible. The risk to bees from residues in succeeding crops could be considered to be covered by an assessment for in-field risk (via residues in nectar, pollen and guttation fluid) for the crops representing potentially high risk (e.g. oilseed rape or maize). However, for an absolute risk assessment it would be necessary to take account of the application rate in the preceding crop, consequent residues in nectar, pollen and guttation fluid, and the type of succeeding crop (i.e. attractiveness, production of guttation fluid). Therefore a data gap was concluded for further assessment of the risk to honey bees foraging in nectar and/or pollen in succeeding crops.

Theoretically, residues in weeds in the treated field could also be a route of exposure to honey bees. However, the risk via this route of exposure 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. This is however not the case for some uses when granular formulations are applied (dispersed) in established crops (see section 3).

Considering the available information in this conclusion, the risk assessments focused on the risk to honey bees via systemic contamination of the treated crop and contamination of other vegetation via dust drift. The risk assessments presented follow a tiered step-wise approach, and data gaps have generally been identified in the overall conclusion for each section (i.e. risk via dust exposure: section 2.1.5, risk via residues in nectar and pollen: section 2.2.6, risk via exposure to guttation fluid: section 2.3.3 and risk for granular products: sections 3.1.5, 3.2 and 3.3).

1. Toxicity endpoints

1.1. Acute toxicity

Several studies were available investigating the acute toxicity of imidacloprid. Since these studies had already been evaluated at EU level and since then no further data overruling the existing endpoints were available, the acute endpoints as reported in EFSA, 2008 will be used in the risk assessment. These data are replicated below.

Acute oral toxicity	LD_{50} = 0.0037 µg a.s./bee (active substance) LD_{50} = 0.0056 µg a.s./bee (formulation)
Acute contact toxicity	LD_{50} = 0.081 µg a.s./bee (active substance) LD_{50} = 0.042 µg a.s./bee (formulation)

Considering all the acute oral laboratory toxicity tests considered in EFSA, 2008, the no observed effect level (based on mortality) is 1.2 ng/bee, as also reported in the Draft Assessment Report (DAR) (Germany, 2005), corresponding to 46 ppb. Regarding acute contact exposure, the reported NOEC was < 2.5 ng/bee (an exact NOEC was not determined).

Data that were available for the EU peer review indicated no considerable difference in the susceptibility of bumble bees to imidacloprid.

It is noted that the formulation data reported above refer to an SL formulation that is less relevant for the evaluation of solid formulations. This is the case also for some newer studies of other formulations where imidacloprid indicated slightly higher toxicity to bees.

1.2. Chronic toxicity

Several data were reported in the DAR regarding the chronic toxicity (the studies were not detailed). This data set indicated NOEC (referred as NOLEC in the DAR) values between 0.1 µg/L and 48 µg/L. The lowest value of 0.1 µg/L was considered to be an unreliable endpoint since it could not be confirmed with additional tests and had some methodological drawbacks. Moreover, these data were not consistent with unpublished and published data investigating chronic dietary toxicity on bees. Excluding this value, the range was 10 µg/L – 48 µg/L, derived from studies where bees were fed with contaminated food for 10, 11 or 15 days. The highest value of 48 µg/L was derived for summer bees, while in another run of the same study winter bees were tested. The run on winter bees resulted in a NOEC of 24 µg/L, as reported in the DAR. That latter value was used further in the DAR and in EFSA, 2008, but expressed as µg/kg (ppm), which is the correct unit based on the original article.

1.3. Sublethal effects

The DAR contained study summaries and information about effects of imidacloprid observed at sublethal doses. A concentration of 20 ppb was found to have effects on foraging behaviour (exposure to sucrose solution in feeders up to 10 days). In other studies, where micro-colonies were fed for 39 days with spiked honey or pollen, no behavioural impacts including parameters for hive development were reported at the level of 20 ppb (see more details about these studies in section 1.5).

A NOEC of 50 ppb and a LOEC of 100 ppb (acute oral exposure) based on conditioned proboscis extension reflex (PER) tests (olfactory memory) were also reported. In chronic PER tests NOEC values of 6 ppb, 10 ppb and 48 ppb were concluded (10 days dietary exposure). The dose of 0.1 ng/bee (acute contact exposure) was concluded to affect the habituation response. From a cage study, treatment-related effects on foraging and feeding behaviour at residue levels of 1.6 ppb were reported, however these findings were considered to be in contradiction to several other reports, and therefore they were not considered further.

The INRA project (see the original DAR; Germany, 2005) concluded a sublethal effect on honey bees, based on olfactory learning performance at 0.004 mg/L equal to 0.13 ng/bee after prolonged oral exposure.

As evaluated in EFSA, 2012b, considerable reduction of foraging activity was described by Schneider *et al*. (2012) at a level of 1.5 ng/bee (115 µg/kg sugar solution) or above, after acute oral exposure. A study by Whitehorn *et al.*, 2012 (also evaluated in EFSA, 2012b) reported colony level effects on bumble bees (*Bombus terrestris*), fed with 6 µg/kg spiked pollen and 0.7 µg/kg spiked sugar solution for two weeks.

1.4. Summary of the toxicological endpoints for adult honey bees

The key toxicological endpoints are summarised in Tables 1 and 2, below.

Table 1 Key endpoints for acute contact exposure of honey bees

Parameter	Endpoint expressed as ng/bee
LD_{50}	81
NOEC based on mortality	< 2.5
effect on habituation	0.1

Table 2 Key endpoints for oral exposure of honey bees

Parameter	Endpoint expressed as dose (ng/bee)	Parameter	Endpoint expressed as concentration (ppb)
acute LD_{50}	3.7	effects on foraging behaviour after acute exposure	115
acute NOEC based on mortality	1.2	acute NOEC based on mortality	46
effects on foraging behaviour after acute exposure	1.5	acute NOEC from PER test	50
chronic NOEC from PER test	0.13	chronic NOEC based on mortality	24
		effects on foraging behaviour after chronic exposure	20
		chronic NOEC for behaviour, including hive development	20
		chronic NOEC from PER test	4*- 48

*: this endpoint refers to µg/L instead of µg/kg

Since no standard test guidelines are available to investigate chronic toxicity or sublethal effects, these results should be considered with caution. Comparison of these results with each other or to interpret their biological/ecological significance is also challenging and uncertain. Nevertheless, considering the results reported above, it may be concluded that effects on foraging behaviour after chronic dietary exposure to 20 ppb cannot be excluded. At that level no effects were seen on colony development, therefore this endpoint may be considered as a worst case if the protection goal is related to effects on colony level (acknowledging that reduced foraging activity can have colony level effects). The acute endpoint for the same parameter (1.5 ng/bee or 115 µg/kg) was already concluded in EFSA, 2012b as an amount not likely to be consumed by a forager honey bee even under worst case conditions.

1.5. Toxicity endpoints on brood

No specific study investigating the effects on brood was available. It is noted however that three studies, already evaluated in the DAR, were considered to be potentially useful to estimate the NOEC for brood.

In the studies of Schmuck and Schöning from 1999 (Germany, 2005), small bee colonies in cages were fed exclusively with either nectar or pollen fortified with technical imidacloprid (at different concentration levels) over 39 days. No treatment-related effects up to 20 ppb were reported on any of the studied parameters that included assessments of brood development. The main drawbacks of these tests were that only one replicate was used and the colonies were very small (approximately 500 bees).

In the study by Faucon *et al.*, 2003 (Germany, 2005), colonies were fed with syrup (13 occasions from July to August, 3 times a week with 1 L/hive), containing imidacloprid at 0.5 or 5 ppb and their summer and winter development was followed. Population development and capped brood area showed a similar development in all colonies with no statistical differences to the control. The study was only very briefly described, the original study report was not available.

1.6. Metabolites

Seven plant metabolites of imidacloprid were identified in different studies. The original DAR concluded that out of these 7 metabolites only the olefine- and the monohydroxy-metabolites are considered to be relevant for seed treatment with imidacloprid. It was shown that these two metabolites have similar toxicity to bees compared to the parent imidacloprid. It is noted that for some other metabolites a considerable repellent effect was reported.

2. Risk assessments for seed dressing products

2.1. Risk from contamination of adjacent vegetation via dust drift

2.1.1. First-tier acute risk assessment

<u>Screening step</u>

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, 2012a suggests to use the full dose (e.g. application rate in g a.s/ha) as a very worst case screening step. The full dose is reached by considering 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 consider the interception by the three-dimensional structured plants. The screening assessments considering the whole application rate are illustrated in Table 3, below. The figures in the table are referring to HQ values (HQ calculations are suggested by EFSA, 2012a even for evaluation of the risk posed by dust) as they were calculated using the formula of deposition (g a.s./ha)/LD_{50} (µg a.s./bee). The LD_{50} values are referring to the technical active substance as reported in the EFSA conclusion on imidacloprid (EFSA, 2008).

Table 3 HQ values calculated using the whole application rate of the lowest and highest ‘maximum application rates’ authorised in the EU, and laboratory LD_{50} values

	LD_{50} contact 0.081 µg a.s./bee	**LD_{50} oral 0.0037 µg a.s./bee**
lowest ‘maximum application rate’ [1] (rape, linseed) = 10 g/ha	123	2703
highest ‘maximum application rate’ (potato) = 1120 g/ha	13827	302703

[1]Where a range of application rates were provided by the Member States for a product, the highest application rate of the range was used for risk assessment. Therefore, the lowest application rate refers to the lowest ‘maximum application rate’ (see Appendix A).

As can be seen from the table above, relatively high HQ values were obtained. If these HQ values are compared with the trigger of 50, as suggested by EFSA, 2012a, a high risk could not be excluded.

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

The risk assessment for honey bees exposed to dust drift was discussed at the Pesticides Peer Review Experts’ Meeting 97. The experts proposed that a risk assessment using the default deposition values for dust drift in the draft ‘Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012[10]’ would be useful. 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 draft ‘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.

The following risk assessments for maize, oilseed rape, cereals and sugar beet uses the proposed default deposition values to adjacent vegetation given in the draft ‘Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012’. The assessment is based on the highest and lowest ‘maximum application rates’ authorised in the EU for each of these uses. The same acute oral and acute contact LD_{50} values, which were used in the screening assessment, were used (Table 3). Table 4 presents the resulting acute HQ values for honey bees foraging in adjacent vegetation following dust emission during the drilling of maize, oilseed rape, cereals and sugar beet.

Table 4 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 ‘maximum application rates’ authorised in the EU for maize, oilseed rape, cereals and sugar beet

Crop	**Parameter**	**Lowest ‘maximum application rate’ authorised in the EU**	**Highest ‘maximum application rate’ authorised in the EU**
Maize	Application rate (g a.s./ha)	54	268

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

Crop	Parameter	Lowest 'maximum application rate' authorised in the EU	Highest 'maximum application rate' authorised in the EU
	% deposition (adjacent vegetation)	7	7
	Predicted off-field deposition rate (g/ha)	3.78	18.76
	Acute oral HQ	1022	5070
	Acute contact HQ	46.7	232
Oilseed rape	Application rate (g a.s./ha)	10	52.5
	% deposition (adjacent vegetation)	2.7	2.7
	Predicted off-field deposition rate (g/ha)	0.27	1.42
	Acute oral HQ	73	383
	Acute contact HQ	3.3	17.5
Cereals	Application rate (g a.s./ha)	63	158
	% deposition (adjacent vegetation)	4.1	4.1
	Predicted off-field deposition rate (g/ha)	2.58	6.48
	Acute oral HQ	698	1751
	Acute contact HQ	31.9	80
Sugar beet	Application rate (g a.s./ha)	18	164
	% deposition (adjacent vegetation)	0.01	0.01
	Predicted off-field deposition rate (g/ha)	0.0018	0.0164
	Acute oral HQ	0.49	4.43
	Acute contact HQ	0.02	0.2

Note: for some uses the authorised application rates were not made available for EFSA, therefore these uses are not covered by these assessments.

As indicated in Table 4, above, the resulting tier 1 HQ values for maize, oilseed rape and cereals are clearly not sufficient to exclude an acute risk to bees foraging in adjacent vegetation following dust emission during the drilling. The resulting tier 1 HQ values for sugar beet for both oral and contact exposure are lower and less than the currently proposed trigger value of 50. Although the trigger value has not yet been agreed, it is considered that the margin of safety obtained in the risk assessment is sufficient to demonstrate low acute risk to honey bees for sugar beet.

The deposition values used to calculate the above HQ values (Table 4) were considered within the draft EFSA guidance document for bees[11] 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 Table 4. Consequently, the resulting HQ values would be 50 % lower, however the outcome of the risk assessment would remain unchanged, except in the case of the lowest 'maximum application rate' authorised for oilseed rape.

2.1.2. First-tier chronic risk assessment

In addition to the HQ calculations to cover acute effects, EFSA, 2012a suggests to calculate 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 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

[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).

residues in nectar and pollen were known, then the daily uptake (knowing the daily consumption of bees) could be estimated. However, information on the residue levels in nectar and pollen occurring after dust drift to adjacent vegetation is not available, and 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.

It is noted that the acute risk assessment for dust drift during the drilling of sugar beet seeds was sufficient to conclude a low acute risk to honey bees. This conclusion was reached based on a risk assessment performed using the default deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012', where it is suggested that only 0.01 % of the in-field application rate will deposit on adjacent vegetation following the drilling of treated sugar beet seeds; this value is noted to be several orders of magnitude less than for other crops such as maize. Although as indicated above, parameters needed to conduct a chronic risk assessment for honey bees foraging on adjacent vegetation are not available, it may be considered reasonable to conclude a low chronic risk to bees for dust emission during the drilling of sugar beet due to the likelihood of very low exposure.

2.1.3. First-tier risk assessment for bee brood

EFSA, 2012a 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 information on the residues in nectar and pollen and the daily larval consumption were known, then the daily uptake could be estimated. Since residue levels in nectar and pollen that may occur after exposure to dust drift to adjacent vegetation are not available, this assessment cannot be performed. Moreover, no reliable endpoint was available for brood (see section 1.5, above).

It is noted that the acute risk assessment for dust drift during the drilling of sugar beet seeds was sufficient to conclude a low acute risk to adult honey bees. This conclusion was reached based on a risk assessment performed using the default deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012', where it is suggested that only 0.01 % of the in-field application rate will deposit on adjacent vegetation following the drilling of treated sugar beet seeds; this value is noted to be several orders of magnitude less than for other crops such as maize. Although as indicated above, parameters needed to conduct a risk assessment for honey bee larvae are not available, it may be considered reasonable to conclude a low risk to bee larvae for dust emission during the drilling of sugar beet due to the likelihood of very low exposure.

2.1.4. Risk assessment using higher tier studies

<u>Tier 2 - higher tier acute risk assessment using refined exposure estimates in adjacent vegetation</u>

As an option for higher tier steps in the risk assessment procedure, EFSA, 2012a suggests to refine the risk assessment by performing field measurements for dust drift. Only two exposure studies for dust drift were available. In one of them the dust deposition of the adjacent off-crop area was monitored at 20 fields under typical agricultural conditions in Germany. <u>Winter barley</u> seeds were sown at rates of 101 - 160 kg/ha, resulting in the application rates of 35.4 - 56 g a.s./ha. In some fields pneumatic machines were used, in others mechanical machines were used (it was not specified whether deflectors or other dust reduction techniques were applied). The contamination of off-crop areas after drilling was measured using Petri dishes as dust traps located outside of the drilled area at different distances. The highest value deposited off-crop was 0.111 g/ha (at about 1 metre from the edge of the field). The 90^{th} percentile deposition was calculated to be 0.046 g/ha at 1 metre. The data indicated a clear decrease in dust drift with the increasing distance (90^{th} percentile deposition was < LOQ at 5 metres). It is noted that several samples with high residues were excluded from the further considerations due to the presence of visible fragments of coated seeds or husks in the Petri dishes and because these large fragments were not considered as relevant for a risk assessment for bees. It is also noted that some dust deposition to off-crop areas can occur with mechanical drillers, although it is mainly attributed to pneumatic machinery.

In the second study, coated cotton seeds were drilled in two sites in Greece. In both sites pneumatic drillers equipped with deflector systems were used. The application rates were 88.84 g a.s./ha and 109.18 g a.s./ha. As in the first study, the contamination of the off-crop areas was measured using Petri dishes at different distances. The highest values deposited at off-crop areas (at 1 metre from the edge of the field) were 49.6 mg a.s./ha and 430.3 mg a.s./ha. The 90th percentile deposition at 1 metre was calculated to be 35.8 mg a.s./ha equivalent to 0.04 %, and 370.6 mg a.s./ha equivalent to 0.339 %. The data indicated a decrease in dust drift with the increasing distance, but positive samples were still found at 50 metres from the treated fields.

Several trials using precision pneumatic seeder machines were performed to measure the dust dispersal of imidacloprid treated maize seeds in the frame of the Italian project 'APENET'. These trials were evaluated in EFSA, 2012c. The magnitude of dust deposition could not be concluded in this evaluation, but it was shown that the dust and therefore the deposition of residues in the off-crop area decreased with the distance; however, no decrease with the distance was apparent in the air concentration (attributed to the fine particles). The dust deposition at soil level could be reduced by 89 % or 95.4 % when the seeder machine was modified with deflector systems that are technological tools to mitigate emission. The reductions in air concentration of imidacloprid were 53.1 % and 72.4 % for the different systems.

Although the available monitoring study in Germany on winter barley (described above) provided useful information on dust drift, the results cannot be used for a reliable risk assessment due to the following limitations:

- The monitoring study was not intended to represent realistic worst case situations in the EU (e.g. 90 % worst case exposure), it rather represents typical situations in Germany. More than half of the trials used mechanical machinery and in several trials only slight wind was measured during the drilling (it is noted that based on the data submitted by the Member States and compiled in Appendix A, no authorisation is registered for cereals in Germany). Moreover, no information is available on the seed coating quality.

- The doses in these field monitoring trials were between 35.4 g and 56 g a.s./ha, while considerably higher application rates are authorised in the EU. Based on the data base in Appendix A, the application rate on cereals is up to 158 g a.s./ha.

- Since one of the factors influencing the abrasion is the crop (seed), extrapolation of these data to other crops is highly uncertain. It would likely be possible for similar cereals (e.g. wheat, oat, rye), but less reliable for all other crops including maize.

However, only for illustration purposes, the deposition of dust to the off-crop area from this monitoring study was compared with the acute toxicological endpoints from the laboratory studies. These assessments are illustrated in Table 5, below.

The conditions of the study conducted using cotton seeds in Greece were considered to be a good representation of typical cotton growing areas in Greece. Imidacloprid is authorised for seed dressing on cotton only in Greece in the EU (based on Member States' feedback, see Appendix A). Therefore the risk assessments based on these field measurements are more reliable. The calculated HQ values for cotton are reported in Table 6, below. It is noted however, as already indicated above, that currently no agreed guidance is available for these refinement steps.

Table 5 HQ values calculated using worst case dust deposition from the German monitoring study and laboratory LD_{50} values

	LD_{50} contact 0.081 µg a.s./bee	**LD_{50} oral 0.0037 µg a.s./bee**
highest measured deposition value = 0.111 g/ha x 10 = 1.11 g/ha	13.7	300
90^{th} percentile deposition value of 0.046 g/ha x 10 = 0.46 g/ha	5.7	124

Note: the factor of 10 is used to take into account the 3-D structure of the plant, for reasoning see section 2.1.1, above

Table 6 HQ values calculated using worst case dust deposition from the study on cotton seeds and laboratory LD_{50} values

	LD_{50} contact 0.081 µg a.s./bee	**LD_{50} oral 0.0037 µg a.s./bee**
highest measured deposition value = 0.43 g/ha x 10 = 4.3 g/ha	53.1	1162
90^{th} percentile deposition value of 0.37 g/ha x 10 = 3.7 g/ha	45.7	1000

Notes:
- the factor of 10 is used to take into account the 3-D structure of the plant, for reasoning see section 2.1.1, above
- the deposition values used in these calculations are referring to the application rate of 109.18 g a.s./ha; while the maximum application rate authorised in the EU is 100 g a.s./ha.

If these HQ values were compared with the trigger of 50 (as suggested by EFSA, 2012a) for oral exposure, high risk could be concluded. The HQ values based on the 90^{th} percentile deposition values indicated a potential low risk for contact exposure (assuming a trigger of 50).

As another option for higher tier steps in the risk assessment procedure, higher tier effect studies may be conducted. No such studies were available with regard to dust exposure, therefore no further assessments could be performed.

2.1.5. Conclusion on the risk via dust drift

Overall, considering the information that is available and the risk assessments that could be performed, it was concluded that high risk resulting from the exposure to dust originating from the drilling procedure cannot be excluded for the authorised uses in the EU. The only exception is **sugar beet**, for which a low risk to honey bees from dust deposition from drilling was concluded for the authorised uses in the EU, on the basis of the tier 1 risk assessments. Assuming the same technology for seed pelleting and drilling, this conclusion was extrapolated also to **fodder beet** and **mangolds**. However it should be noted that these conclusions are based on default deposition values proposed in the draft ‘Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012’.

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) to bees for situations where bees forage on vegetation exposed to dust drift emitted during the drilling procedure for **all the uses** evaluated **except for beet crops**.

It should be noted however, that these conservative assessments are focussing 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 to dust drift is dependent on some landscape factors such as the occurrence and distribution of attractive plants around the drilled area or the used machinery (e.g. type of drilling machine or the use of deflector systems to mitigate emission). The deposition values used to calculate the tier 1 HQ values (section 2.1.1, above) 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 2.1.1, above. Consequently, the resulting HQ values would be 50 % lower however, the outcome of the risk assessment would remain unchanged, except in the case of the lowest 'maximum application rate' authorised for oilseed rape.

The GAP tables did not specify whether any crops would be planted in glasshouses and subsequently transplanted to the field (as may be the practice for some vegetables in some Member States). However, if seeds are planted indoors then, due to negligible exposure, the risk to bees via dust drift exposure is negligible.

It should also be noted that the above assessments do not specifically consider the potential risk to honey bees from relevant sublethal effects following exposure via dust drift. Currently there is no agreed testing strategy for 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.

EFSA, 2012c also concluded that forager bees are at risk when they fly through the dust clouds emitted by conventional seeders sowing maize seeds coated with imidacloprid. That confirms the conclusions and the data gap above.

It is noted that several experiments were conducted in Germany on dust drift with seeds treated mainly with clothianidin (Heimbach, U., *et al.*; 2012; Georgiadis *et al*., 2012a, 2012b; Pistorius, J. *et al*., 2012), and a publication of Forster *et al.*, 2012 on data obtained from different research facilities. These data were considered during the Pesticides Peer Review Experts' Meeting 97 and were summarised in the EFSA conclusion for clothianidin evaluated under the current mandate.

It was considered at the Pesticides Peer Review Experts' Meeting 97 that the available data for foliar spray applications might be extrapolated to perform some kind of risk characterisation for dust exposure, if a considerable margin of safety exists. Since the available data for foliar spray applications were not assessed in the current evaluation, it was not possible to perform such an assessment in the framework of the current mandate.

2.2. Risk via systemic translocation in plants – residues in nectar and pollen (including sublethal effects)

Information on the residue levels occurring in nectar and pollen was collected and reported in EFSA, 2012a and EFSA, 2012b. This database was amended and further improved (derivation of residue unit doses) for the draft EFSA guidance document on bee risk assessment and for the current mandate for neonicotinoids. Regarding imidacloprid, information from 29 outdoor studies (some studies included more than one trial) on 4 crops (oilseed rape (one overseas study on canola), sunflower, maize and cotton) were available in this database. To ease the risk assessment, these residue values need to be expressed as RUD (residue unit dose) to make them independent from the application rate used in the studies. Only a few studies allowed RUD calculations, i.e. those where residues were detected > LOD and detailed information on the application rate was available. These values are reported in Appendix I of the draft guidance document on bee risk assessment. This list of data was amended (e.g. with data for cotton that were not available to EFSA earlier) and summarised in Table 7, below. It was noted that in the majority of the residue studies, imidacloprid residues were < LOD or < LOQ,

[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).

however it is also noted that in several of these cases a relatively high LOQ was used (i.e. 0.01 mg/kg). The maximum measured residues were the bases of the RUD calculations.

Table 7 RUD values of imidacloprid for pollen and nectar referring to an application rate of 1 kg/ha or 1 mg/seed

	RUD for pollen	RUD for nectar
Oilseed rape	0.069-0.156 mg/kg based on application rate of 1 kg/ha	0.017-0.159 mg/kg based on application rate of 1 kg/ha
Sunflower	0.004-0.036 mg/kg based on seed dressing rate of 1 mg/seed	no RUD value available
Maize	0.056 mg/kg based on application rate of 1 kg/ha; 0.002-0.006 mg/kg based on seed dressing rate of 1 mg/seed	Not applicable
Cotton	0.023-0.046 mg/kg based on application rate of 1 kg/ha; 0.004-0.009 mg/kg based on seed dressing rate of 1 mg/seed	0.045-0.046 mg/kg based on application rate of 1 kg/ha; 0.008-0.009 mg/kg based on seed dressing rate of 1 mg/seed

Notes: - whether a RUD value refers to 1 kg/ha or 1 mg/seed depends on the information that was available on the respective studies;
- the data on nectar of cotton based on extra floral nectar as residues in this matrix were higher than in nectar within the flower

The level of residues that are expected to be present in nectar and pollen via root uptake and systemic distribution in the plant is crop dependent. Therefore, extrapolation from one crop to another is highly uncertain, and a risk assessment can only be performed for those crops for which residue data are available. As residue data were not available for all of the authorised crops in the EU, no first-tier risk assessment could be performed for crops other than maize, sunflower, cotton and oilseed rape. Moreover, in order to achieve a worst case risk assessment it should be demonstrated that the conditions of the studies are worst case in terms of residue formation. As information is not available to support the severity of the conditions in the studies there is uncertainty as to whether the RUD values are suitably worst case. It is noted also that for some crops (e.g. cotton) only a limited number of studies were available.

However, the risk to pollinators also depends on other factors (e.g. landscape factors). The most important of these, which is also crop-dependent, is the attractiveness of the crop. Some of the crops on which imidacloprid is authorised as a seed-dressing do not flower, are harvested before flowering, or do not produce nectar or pollen. Therefore these crops will not pose any risk to bees via this route of exposure. In the Table 8 below, the crops on which imidacloprid is authorised are separated based on their attractiveness to honey bees. This allocation is based on the list compiled in the Netherlands for the same purposes (Ctgb, 2011). Some specific crops, relevant for this evaluation, were not included in this list and therefore the assessment of the attractiveness to honey bees (Table 8) was based on the crop category which was included in the list. The list of non-attractive crops should not be extrapolated to crops which are grown for seed-production as in these circumstances the plants will be allowed to flower, and therefore can be attractive to bees (e.g. onion in the second year). It should be noted that the attractiveness of a crop to honey bees is not necessarily the same to other pollinators. Potato flowers for example are indicated as non-attractive to honey bees, but it is known that some bumble bee species collect pollen from potato flowers. Also, the list focuses on attractiveness to nectar or pollen and does not take into account other matrices such as guttation fluids (see evaluation in section 2.3, below) or honey dew. The risk from exposure to honey dew excreted from aphids was considered as low by EFSA, 2008, since it was indicated that imidacloprid was considerably more toxic (with several orders of magnitude) to aphids than to bees. However the derivation of the toxicity endpoints for aphids was not clear, and therefore a data gap to clarify this point was identified. Since this clarification was not available and evaluated at EU level, this data gap was confirmed to be still relevant. It is noted moreover that apart from aphids, other insects may also produce honey dew.

Table 8 Attractiveness of agricultural crops (for which imidacloprid seed treatment authorisation is granted) to honey bees for the collection of nectar and/or pollen

Attractive and nectar or pollen may be collected by bees	Non-attractive to bees (for nectar or pollen)			
asparagus	headed brassicas	Chinese cabbage	onion	cereals
cotton	leafy brassicas	Brussels sprouts	leek	wheat
maize (corn)	head cabbage	lettuce	potato	barley
oilseed rape	kohlrabi	endive	beets	oat
sunflower	kale	radicchio rosso	sugar beet	
pumpkin	broccoli	sugar loaf	fodder beet	
linseed (flax)	cauliflower	bulb crops	mangolds	

2.2.1. First-tier acute risk assessment

EFSA, 2012a 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 imidacloprid can be estimated.

Regarding the feed consumption, EFSA, 2012a reported data for different castes of bees. As a worst case for adult honey bee, 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:

$$RI_{forager} = \frac{Rn \text{ x } Cn}{1000}$$

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

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)

Oilseed rape

Based on the data submitted by the Member States, imidacloprid is authorised in 9 EU countries for use as a seed-dressing under different product names (see Appendix A). The doses are between 10 and 52.5 g a.s./ha[13]. Considering these doses and the highest available RUD values from Table 7, the calculated residue levels (expressed in µg/kg) in nectar are between 1.59 and 8.35 µg/kg, and for pollen they are between 1.56 and 8.19 µg/kg. Assuming 15 % as a realistic worst case estimation for sugar content of oilseed rape 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. Using the calculated residues and the higher value for consumption, the residue intake (RI) (expressed in ng/bee/day) was calculated to be between 1.357 – 7.124 ng/bee/day for a forager and between 0.549 – 2.881 ng/bee/day for a nurse bee for the lowest and highest ‘maximum application rate’, respectively. Considering these ingestion rates, the ETR values reported in Table 9 below were derived.

Table 9 ETR_{acute} values for the authorised uses on oilseed rape

Application rate	ETR_{acute} forager bee	ETR_{acute} nurse bee
lowest ‘maximum application rate’ = 10 g a.s./ha	0.37	0.15
highest ‘maximum application rate’ = 52.5 g a.s./ha	1.93	0.78

Sunflower

Based on the data submitted by the Member States, imidacloprid is authorised only in one EU country for use as a seed-dressing with the dose rates of 24 - 35 g a.s./ha or 0.7 mg a.s./seed, under the product name of ‘Gaucho 600 FS’ (see Appendix A). Considering that no RUD values could be calculated for nectar, but residue formation in sunflower nectar cannot be excluded (in two studies < LOQ was reported), other data than those reported in Table 7 were used. The highest residues in nectar and pollen were determined in studies (Stork, 1999; Germany, 2005; Schmuck *et al.*, 2001; EFSA, 2012a), where sunflowers were grown in greenhouse. The application rate was 0.787 mg/seed or 0.7 mg/seed, and the corresponding residues were 0.0019 mg/kg in nectar and 0.0033 mg/kg in pollen, and 0.0019 mg/kg in nectar and 0.0039 mg/kg in pollen, respectively for the two slightly different application rates. Considering the authorised application rate of 0.7 mg/seed, the residues (expressed in µg/kg) of 1.9 µg/kg in nectar and 3.9 µg/kg in pollen can directly be used. Assuming the same nectar consumption as for oilseed rape (213 - 853 mg/bee/day), the residue intake (RI) (expressed in ng/bee/day) was calculated to be 1.621 ng/bee/day for a forager and 0.68 ng/bee/day for a nurse bee. Considering these ingestion rates the ETR values reported in Table 10 below were derived.

Table 10 ETR_{acute} values for the authorised uses on sunflower

Application rate	ETR_{acute} forager bee	ETR_{acute} nurse bee
application rate = 0.7 mg/seed	0.44	0.18

Maize

Based on the data submitted by the Member States, imidacloprid is authorised in 10 EU countries for use as a seed-dressing under different product names (see Appendix A). The doses are between 54 and 268 g a.s./ha[14]. Considering these doses and the available RUD value from Table 7, the calculated

[13] considering the lowest and highest ‘maximum application rates’, see Appendix A
[14] considering the lowest and highest ‘maximum application rates’, see Appendix A

residue levels (expressed in µg/kg) in pollen were between 3.02 and 15.01 µg/kg. Using the calculated 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 0.036 – 0.180 ng/bee/day for the lowest and highest ‘maximum application rates’. Considering these ingestion rates the ETR values reported in Table 11 below were derived.

Table 11 ETR_{acute} values for the authorised uses on maize

Application rate	ETR_{acute} nurse bee
lowest ‘maximum application rate’ = 54 g/ha	0.01
highest ‘maximum application rate’ = 268 g/ha	0.05

Cotton

Based on the data submitted by the Member States, imidacloprid is authorised only in one EU country for use as a seed-dressing with the dose rates of 75 - 100 g a.s./ha, under different product names (see Appendix A). Considering these doses and the highest available RUD values from Table 7, the calculated residue levels (expressed in µg/kg) in nectar and pollen are between 3.45 and 4.6 µg/kg. Assuming the same nectar consumption as for oilseed rape, the residue intake (RI) (expressed in ng/bee/day) was calculated to be 3.925 ng/bee/day for a forager and 1.589 ng/bee/day for a nurse bee. Considering these ingestion rates the ETR values reported in Table 12 below were derived.

Table 12 ETR_{acute} values for the authorised uses on cotton

Application rate	ETR_{acute} forager bee	ETR_{acute} nurse bee
lowest application rate = 75 g/ha	0.8	0.32
highest application rate = 100 g/ha	1.06	0.43

Notes regarding the assessments:

- The risk assessment was based on the highest application rates for oilseed rape and maize in the countries where imidacloprid is authorised. For cotton the maximum and minimum application rates were used which were noted in the relevant country. For sunflower, a single application rate, expressed in terms of mg a.s./seed, was used.

- The highest residues where RUD calculations could be done were used for these assessments (except sunflower). In reality, the levels of residues have a large variation. RUD values were also calculated considering the LOQ for cases where the measured residues were between LOD and LOQ. The data set for RUD values did not distinguish winter and summer oilseed rape (e.g., the RUD for pollen originates from a study on summer oilseed rape, which might lead to an overestimation of the residue levels for use in a risk assessment for winter oilseed rape).

- In case of sunflower, the residue data were taken from a study that is not considered to be representative for field realistic situations. In this greenhouse study, a higher residue level was measured for nectar than in outdoor studies, but lower for pollen. In fact, imidacloprid was not detected in nectar in any of the outdoor studies that were available (one study reported residue < LOQ, but it was not reported whether the residue was > LOD).

- The data set for residues consisted of 11 studies for oilseed rape, 7 for maize, 10 for sunflower and only 1 for cotton (on 2 sites). The data set for sunflower contains data from Argentina, the data set for rape (canola) contains some data originating from the USA or Canada. In the majority of the residue studies imidacloprid was measured < LOD or < LOQ, but also, in several cases a relatively high LOQ was used.

- The 2 trials for cotton likely originate from typical cotton-growing areas from Greece.

- The severity of the data set for residues could not be evaluated (i.e. to assess whether the studies represented realistic worst case situations in terms of residue formation in nectar and pollen).

- The worst case nectar and pollen consumption was taken into account, and for the calculations of the nectar consumption, worst case sugar content was considered. In reality, both factors have a large variation. For example, sunflower nectar has usually higher sugar content than the used 15 %.

2.2.2. First-tier chronic risk assessment

EFSA, 2012a suggests to calculate 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, 2012a, should originate from a 10-day dietary study on adult bees. No such LC_{50} value was available for imidacloprid, but a NOEC of 24 µg/kg from similar studies was concluded in the DAR and in EFSA, 2008. Currently no practical guidance is formally available regarding the estimation of the ingestion rate of residues or regarding the comparison of this estimation to the toxicological endpoint. However, if the residues in nectar and pollen and the daily consumption of bees, as described in EFSA, 2012a, are known, then the daily uptake of imidacloprid could be estimated (as was done for the acute risk assessments).

Since the available endpoint (NOEC) is expressed in terms of a concentration in the food (µg/kg) rather than a daily uptake value (µg/bee/day), these assessments cannot be performed. However, to make best-use of the available data for imidacloprid, an illustrative assessment can be performed by direct comparison of the concentration in relevant matrices (pollen and nectar) to the available NOEC value in terms of µg/kg. It must be noted that this surrogate assessment does not account for actual intake of the bee and consequently should not be considered as a definitive risk assessment. The experts at the Pesticides Peer Review Experts' Meeting 97 highlighted a concern over the surrogate assessment, performed using concentrations, because it might be less conservative than if actual intake of the bees was accounted for. As described previously, the assessment should only be considered for illustrative purposes but is included to provide a better understanding of the risk posed by imidacloprid.

Since forager bees consume only nectar, the estimated residue levels in nectar can directly be compared with the toxicity endpoint. These comparisons are illustrated in Table 13, below. For nurse bees, the residue concentrations (in the mix of pollen and nectar) need to be calculated and these concentrations can be compared with the toxicity endpoint. This combined concentration can be calculated by using the following formula:

$$RC = \frac{(Rn \text{ x } Cn) + (Rp \text{ x } Cp)}{Cn + Cp}$$

Where: RC is the concentration of residues in the mixed diet expressed in mg/kg
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)

As already indicated above, the sugar and pollen consumption of a nurse bee is reported as a range, and since only the energy demand is available, the nectar consumption needs first to be calculated. The smaller value of the ratio of nectar and pollen consumption will be the worst case for sunflower and maize, as for these crops the higher residue levels were found in pollen. It is noted that the residue levels for sunflower originate from greenhouse studies (see section 2.2.1, above) and for maize 0 mg/kg will be considered as the residue level in nectar. In contrast, for oilseed rape, where the highest residue level was higher in nectar than in pollen, the higher nectar consumption (the higher nectar/pollen ratio) will be the worst case. For cotton, the ratio of nectar and pollen consumption will not affect the concentration of the mixed diet since the residue level was the same in both matrices.

The lower estimated nectar consumption was calculated assuming the daily sugar demand of 34 mg and a nectar sugar content of 65 %. This resulted in 52.3 mg daily nectar consumption, which was combined with the highest pollen consumption of 12 mg/day. These parameters were used for the assessments for sunflower and maize. For oilseed rape, the daily sugar demand of 50 mg was combined with a nectar sugar content of 15 % and a pollen consumption of 6.5 mg/day. These calculated overall residue concentrations were compared with the toxicological (µg/kg) endpoint as illustrated in Tables 13 and 14, below.

Table 13 Comparison of the residue levels in nectar to the toxicological endpoint for the risk assessment for foragers

	Oilseed rape	**Sunflower**	**Cotton**
Residue level for the lowest 'maximum application rate'	1.59 µg/kg	1.9 µg/kg	3.45 µg/kg
Residue level for the highest 'maximum application rate'	8.35 µg/kg		4.6 µg/kg
Chronic endpoint (NOEC)	**24 µg/kg**		
Ratio (NOEC/residue) for the lowest 'maximum application rate'	15.1	12.6	7.0
Ratio (NOEC/residue) for the highest 'maximum application rate'	2.9		5.2

Table 14 The calculated residue levels in the mixed diet of nurse bees and the comparison of these levels to the toxicological endpoint

	Oilseed rape	**Sunflower**	**Maize**	**Cotton**
Residue level (RC) for the lowest 'maximum application rate'	1.58 µg/kg	2.27 µg/kg	0.56 µg/kg	3.45 µg/kg
Residue level (RC) for the highest 'maximum application rate'	8.32 µg/kg		2.8 µg/kg	4.6 µg/kg
Chronic endpoint (NOEC)	**24 µg/kg**			
Ratio (NOEC/RC) for the lowest 'maximum application rate'	15.1	10.6	42.6	7.0
Ratio (NOEC/RC) for the highest 'maximum application rate'	2.9		8.6	5.2

The estimated concentrations in bee relevant matrices are lower than the chronic NOEC of 24 µg/kg. This could be interpreted to indicate a low chronic risk to adult bees for oilseed rape, sunflower, maize and cotton, if a safety factor of 2.9, 10.6, 8.6 and 5.2, respectively, is considered sufficient.

However, it must be noted that the above risk assessment was only included as an illustrative assessment and was not performed in accordance with EFSA 2012a where it is recommended that consumption is accounted for. Therefore, care must be taken with the interpretation of the above risk assessment.

Notes regarding the uncertainty of these assessments:

- No standard test methodology is available for chronic tests. The toxicological endpoint of 24 µg/kg originates from the open literature and from studies not conducted under the GLP rules (see more details above).

- Regarding the estimation of exposure, the same issues for uncertainty already identified in the acute evaluation (see section 2.2.1 above) are also relevant.

- The risk characterisation was only a kind of surrogate assessment and cannot be considered as a definitive risk assessment.

2.2.3. First-tier risk assessment for brood

EFSA, 2012a 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). Currently no practical guidance is formally available regarding the estimation of the ingestion rate of residues or regarding the comparison of this estimation to the toxicological endpoint. Similar assessments as those conducted for the chronic assessments could be performed, however, in the absence of a reliable toxicological endpoint (see section 1.5, above), no risk assessment for larvae could be performed.

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

Currently, there is no agreed testing strategy for 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, several sublethal endpoints were available for imidacloprid, these are summarised in Table 2, above. As explained in section 1.4, the endpoint of 20 ppb (µg/kg) was identified as the most relevant sublethal endpoint for further considerations. Assessments using the same approach (therefore bearing the same uncertainty) as for the chronic risk assessment were followed. This is illustrated in Tables 15 and 16, below.

Table 15 Comparison of the residue levels in nectar with the endpoint for the risk assessment for foragers

<table>
<tr><th></th><th>Oilseed rape</th><th>Sunflower</th><th>Cotton</th></tr>
<tr><td>Residue level for the lowest ‘maximum application rate’</td><td>1.59 µg/kg</td><td rowspan="2">1.9 µg/kg</td><td>3.45 µg/kg</td></tr>
<tr><td>Residue level for the highest application rate</td><td>8.35 µg/kg</td><td>4.6 µg/kg</td></tr>
<tr><td>Chronic endpoint (NOEC)</td><td colspan="3">20 µg/kg</td></tr>
<tr><td>Ratio (NOEC/residue) for the lowest ‘maximum application rate’</td><td>12.6</td><td rowspan="2">10.5</td><td>5.8</td></tr>
<tr><td>Ratio (NOEC/residue) for the highest ‘maximum application rate’</td><td>2.4</td><td>4.3</td></tr>
</table>

Table 16 The calculated residue levels in the mixed diet of nurse bees and the comparison of these levels with the endpoint

	Oilseed rape	Sunflower	Maize	Cotton
Residue level (RC) for the lowest application rate	1.58 µg/kg	2.27 µg/kg	0.56 µg/kg	3.45 µg/kg
Residue level (RC) for the highest application rate	8.32 µg/kg		2.8 µg/kg	4.6 µg/kg
Chronic endpoint (NOEC)	**20 µg/kg**			
Ratio (NOEC/RC) for the lowest 'maximum application rate'	12.6	8.8	35.5	5.8
Ratio (NOEC/RC) for the highest 'maximum application rate'	2.4		7.1	4.3

The estimated concentrations in bee relevant matrices for oilseed rape, sunflower, maize and cotton are somewhat lower than the chronic endpoint, where some effects on foraging behaviour were observed in a study, but no effects were seen on colony development in another study. No assessment could be made for the other attractive crops, such as asparagus, pumpkin or linseed.

2.2.5. Risk assessment using higher tier studies

Numerous higher tier semi-field and field studies were available for oilseed rape and sunflower. Several of them were already reported in the DAR and evaluated at EU level (EFSA, 2008), and were reconsidered for the present conclusion in view of EFSA 2012a.

Clear effects were not observed in any of the studies. There were some indications of potential effects (e.g. increased mortality or slightly lower hive weight gain compared to the control), but in none of the cases could they be attributed to exposure to imidacloprid with high certainty. All studies had drawbacks, for example one or more of the following: short exposure or short post-exposure follow-up period; unclear reporting or no information about some important parameters; use of other insecticides (i.e. fipronil) in or close to the test fields; low number of replicates; lack of statistical evaluations; too small colonies; food stock was not removed to ensure the use of freshly collected food; lack of residue analysis or low residue levels in relevant matrices compared with available data; attractive alternative food sources in the vicinity of the fields; likelihood of cross-foraging between treated and control fields; lack of pollen source analysis or analysis indicated relatively low ratio of relevant pollen type. 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 imidacloprid as a seed treatment in oilseed rape or sunflower. It must be borne in mind that in some of these studies the exposure of bees was evaluated as potentially high (e.g. considerably high foraging activity on the treated plots). Moreover, some other studies (see short description in section 1.5, above), where bee colonies were fed with spiked pollen or nectar, also represented potentially high exposure. However, these studies had also drawbacks.

Overall, considering that numerous higher tier studies were made available, it might be concluded that the studies encompassed several agricultural situations considered to be typical for Europe. However, whether any of these studies were realistic worst case, could not be proved.

2.2.6. Conclusion on the risk via systemic translocation in plants – residues in nectar and pollen (including sublethal effects)

A low risk was concluded for a number of crops, which are not foraged for pollen or nectar by bees (see a list of these crops in Table 8, above). However, imidacloprid is authorised for use on seven bee attractive crops. Essential information (levels of residues in nectar and pollen) was missing for risk assessments, therefore a data gap was identified for further assessments to address the risk (i.e. the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk following exposure to sublethal doses) for **asparagus, pumpkin** and **linseed**. For **maize, oilseed rape, sunflower** and **cotton**, first-tier risk assessments for the EU authorised uses were conducted. The ETR values for acute exposure of adult bees were between 0.37 and 1.93 for oilseed rape, sunflower and cotton. This means that the calculated intake is close to or above the oral LD_{50} value (an ETR of 1 would show that they are equal), therefore a data gap was identified for these three crops. In case of maize the ETR values were between 0.01 and 0.05, indicating a margin of safety.

Therefore these calculations indicated a potential acute risk, at least for oilseed rape, sunflower and cotton (for information: the acute NOEC based on mortality is about 3 times lower than the LD_{50}). It must be borne in mind that the residue intake estimations represent worst case scenarios. Further higher tier refinements might be performed. For example, data on metabolism in bees, dilution factors, or specific sugar content for the crops could be considered, but no agreed approaches are currently available. It should also be noted that the highest available residue levels were used for the intake estimations. This was clearly worst case for sunflower nectar.

Chronic risk assessments, where the calculated residue levels in the feed of the bees were compared with the NOEC value of an available dietary test, were also conducted for the same crops. This indicated a margin of safety between 2.9 - 10.6 for these four crops. However, it is noted that these assessments were only conducted for illustrative purposes and should not be considered as a definitive risk assessment.

Similar assessments were conducted with a slightly lower sublethal chronic endpoint, where effects on foraging were observed, but there was no impact on colony development. The margin of safety ranged between 2.4 – 8.8 for these four attractive crops.

Again, these calculations were based on worst case approaches and the toxicity endpoints are also uncertain since currently no harmonised or internationally recognised test guidelines are available for chronic toxicity (either for lethal or sublethal effects).

Since no reliable endpoint was available for brood, a data gap for risk assessments for bee brood was identified for the **attractive crops** (see Table 8).

Higher tier (semi-field and field) studies were available for **oilseed rape** and **sunflower** (likely the most attractive field crops to bees). All of these studies had drawbacks (see section 2.2.5, above), and therefore they were not sufficient to demonstrate that the risk to bees was low for the use of imidacloprid as a seed treatment in oilseed rape or sunflower.

2.3. Risk via systemic translocation in plants – guttation

2.3.1. First-tier risk assessment

EFSA 2012a indicates that ETR_{acute}, ETR_{adult} 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. As a form of screening step, to understand the potential risk to bees, a comparison of the acute toxicity of imidacloprid with the concentrations that may be 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 imidacloprid to honey bees is 0.0037 µg a.s./bee. No study was available indicating concentrations of imidacloprid that may occur in guttation droplets. However data on other neonicotinoids with similar physical-chemical properties (i.e. thiamethoxam and clothianidin) indicated that concentrations up to some hundred mg/L can occur. This is in line with several recently published data. For example, Forster (2011) indicated that concentrations of neonicotinoids in the guttation drops of field crops may be very high for around 8 to 9 weeks. The water solubility of imidacloprid is around 600 mg/L (EFSA, 2008) and water solubility is relatively insensitive to the pH. Therefore it is unlikely that the concentration of imidacloprid will be higher than 600 mg/L in the guttation fluid.

Using this conservative estimation, it can be calculated that a honey bee would have to consume about 0.006 µL of guttation fluid to reach the acute oral LD_{50}.

A water forager can perform 46 trips per day on average (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, 2012a).

On the basis of these calculations, it is clear that the concentrations that may be found in guttation fluid could potentially pose a concern to bees if there is exposure to guttation fluid.

2.3.2. Risk assessment using higher tier studies

No studies specifically investigating exposure or effects on bees for imidacloprid treated seeds were available.

Only some brief summaries of studies investigating the relevance of guttation were available. These confirmed that guttation fluid may contain high residue levels of pesticides and concluded that guttation regularly occurs in maize, less frequently in potato, and hardly in sugar beet.

<u>Additional information</u>

During the Pesticides Peer Review Experts' Meeting 97 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 all conducted with plant protection products containing clothianidin and therefore were not directly relevant to the risk assessment for plant protection products containing imidacloprid. Nevertheless, the general conclusions may be useful. 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. With regard to the effects observed, it was noted that in a few situations in maize a peak of mortality was observed. However, mortality was not observed in the majority of studies. No long-term effects on the colony were reported.

Bees were not observed to collect guttation fluid from triticale and maize (by Reetz *et al*. 2011). In addition, Schneider *et al.,* 2012 reported that the relevance of guttation exposure is still unclear. Girolami *et al.,* 2009, in a paper investigating the residue levels of imidacloprid, clothianidin and thiamethoxam and their toxicity, by offering contaminated guttation droplets to honey bees, concluded that the likelihood that bees could drink from maize or other crops' guttation drops is not yet quantified, and therefore it is not possible to make a judgment on a possible correlation between neonicotinoid translocation in guttation drops and Colony Collapse Disorder. This conclusion was also supported by some experiments within the APENET project (considered in EFSA 2012c). For example Tapparo *et al*, 2011 concluded that the risk from guttation is affected by several factors that cause a high variability both in intensity of guttation events and in the residue levels, and therefore further experiments would be needed to understand the phenomenon and its consequence in the risk assessment.

2.3.3. Conclusion on the risk via systemic translocation – guttation

A high risk cannot be excluded for imidacloprid treated crops if guttation occurs.

It was acknowledged that there is evidence to suggest that crops will vary in the intensity and frequency of occurrence of guttation events (e.g. sugar beet and carrot are thought to infrequently guttate). However, no quantified data were available regarding the occurrence of guttation fluid in different crops, and therefore it is not possible to conclude on the risk to honey bees. A data gap was concluded for information to address the exposure, and hence the risk (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood) to bees from exposure via guttation fluid for **all the crops** for which imidacloprid is authorised as a seed treatment.

The experts at the Pesticides Peer Review Experts' Meeting 97 discussed the feasibility of risk mitigation measures to reduce the risk to bees from exposure via guttation fluid. The experts considered that it could be problematic to recommend that other water sources should be made available to bees as it may increase disease transmission. Furthermore, it is not known whether offering an alternative water source would result in the bees no longer using guttation fluid, and hence would be effective in mitigating the risk. The experts were also concerned with the practicalities of compliance.

3. Risk assessments for granules

According to the information provided by the Member States, imidacloprid is authorised in five different granular products and used in a variety of amenity turf, forestry, horticultural, home garden and public grass situations (see Appendix A).

3.1. Risk from contamination of neighbouring vegetation via dust drift

Considering the application techniques or the indoor uses, for the products 'Suxon Forest' and 'Suscon H&G', a low risk for pollinators was concluded. The product 'Suscon' may also be used indoors resulting in a low risk to pollinators. However, due to the application techniques, dust emission, and therefore exposure of adjacent areas cannot be excluded for the uses of 'Merit Turf', or dust being deposited onto flowering plants in the garden during the use of 'Lotus Granuli' in home garden lawn. Also, for the uses when 'Lotus Granuli' and 'Suscon' is blended with the soil substrate using machinery outdoors, dust formation and exposure of adjacent areas cannot be excluded. It is noted that during the Pesticides Peer Review Experts' Meeting 97 the expert from the Netherlands indicated that low dust exposure is expected from the uses of 'Merit Turf' in the Netherlands. This was however only supported by some data on potential attrition of the formulation.

3.1.1. First-tier acute risk assessment

In line with the recommendations of EFSA 2012a, a first-tier risk assessment for honey bees can be performed by calculation of a HQ, using the acute contact and oral LD_{50} values (µg a.s./bee) and the in-field application rate (in terms of g a.s./ha). However, calculation of a first-tier HQ is not appropriate and was not conducted for some of the uses of imidacloprid granules authorised in the EU, as the application rate has only been provided in terms of volume of the substrate. Using an acute oral LD_{50} value of 0.0037 µg a.s./bee and an acute contact LD_{50} of 0.081 µg a.s./bee, first-tier HQ values were calculated and presented in Table 17.

Table 17 HQ values calculated for EU authorised uses of imidacloprid granular products*

Product	Use	Maximum application rate g a.s./ha	Acute oral HQ	Acute contact HQ
'Lotus Granuli'	Home garden lawn	125	33784	1543
'Merit Turf'	Public grass and vegetation	150	40541	1852
'Merit Turf'	Turf	150	40541	1852
'Merit Turf'	Managed amenity turf (golf courses, sports grounds, commercial and residential lawns)	150	40541	1852

* only uses are presented for which application rate data were available and low risk could not be concluded on the basis of the application techniques/indoor uses

The resulting HQ values are all high and therefore are not considered sufficient to demonstrate a low risk to honey bees from exposure via dust drift.

3.1.2. First-tier chronic risk assessment

In addition to the HQ calculations to cover acute effects, EFSA, 2012a suggests to calculate a chronic ETR_{adult} between the amount of residues that may be ingested by an adult bee in 1 day and the LC_{50} value. To conduct such assessments, the uptake rate of a bee should be estimated after foraging on crops exposed to dust drift. Residue levels in nectar and pollen that may occur after dust exposure are not available and currently no official guidance is available for these estimations. Therefore this assessment cannot be performed.

3.1.3. First-tier risk assessment for brood

EFSA, 2012a 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. Since residue levels in nectar and pollen that may occur after dust exposure are not available and currently no official guidance is available for these estimations, this assessment cannot be performed. Also, no toxicity endpoint for larvae was available and therefore a data gap was identified.

3.1.4. Risk assessment using higher tier studies

No higher tier studies were available to refine the assessment for exposure or for the potential effects of dust drift of granular formulations to honey bees, therefore no refined risk assessment could be performed.

3.1.5. Conclusion on the risk via dust drift

Dust formation and high risk cannot be excluded, and therefore a data gap was identified to address the risk to honey bees (i.e. the acute and long-term risk on colony survival, development and the risk for bee brood) from dust drift for 'Merit Turf', 'Lotus Granuli' and 'Suscon' when the granules are blended with the soil substrate using machinery outdoors.

Low risk for pollinators was concluded for the products 'Suxon Forest' and 'Suscon H&G', and for the product 'Suscon' when it is used indoors.

3.2. Risk via systemic translocation in plants – residues in nectar and pollen

No nectar and pollen residue data are available for plants treated with the authorised imidacloprid granular products. The level of residues that are expected to be in nectar and pollen via root uptake and systemic distribution is plant-dependent and may also depend on the formulation and the application technique. Extrapolation of residues from other types of plant, formulation or crop is highly uncertain. Therefore, a quantitative risk assessment for honey bees foraging in plants treated with imidacloprid granules cannot be performed.

The authorised uses of imidacloprid granules on **ornamental plants** ('Suscon' and 'Lotus Granuli') are considered to pose a potential risk to pollinators foraging in treated plants that may flower later in the season and kept outdoors. Therefore, a data gap was identified to address the risk (i.e. the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk following exposure to sublethal doses) for these situations. Imidacloprid granules are also authorised for application to amenity turf, turf and home garden lawns or public grass vegetation ('Merit Turf' and 'Lotus Granuli'). As the presence of flowering weeds cannot be excluded in turf, home garden lawns or public grass vegetation, a potential risk to bees foraging on flowering weeds cannot be excluded. Therefore a data gap was identified to address the risk (i.e. the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk following exposure to sublethal doses) to bees foraging on flowering weeds in **amenity turf, turf, home garden lawns** and **public grass vegetation**. In highly managed amenity turf, such as golf greens and professional sports grounds, flowering weeds are unlikely to occur and hence a low risk to pollinators could be concluded in these situations. 'Suxon Forest' is authorised for use on tree seedlings in forestry situations in France. Since the granules will only be applied to young tree seedlings a significant time before they begin to flower, a low risk was concluded for these situations. The use of 'Suscon H&G' as a granule on flowers and ornamental plants in Italy was indicated to be indoors only, therefore a low risk was concluded.

3.3. Risk via systemic translocation in plants – guttation

Grasses, some trees and ornamental plants are known to produce guttation fluid under certain circumstances. Information as regards whether pollinators will use guttation fluid from nursery trees, ornamental plants, turf, amenity turf and home garden lawns is not available. When guttation fluids are collected by bees, high risk cannot be excluded (see section 2.3, above). Therefore, a data gap to address the risk (i.e. the acute and long-term risk to colony survival and development, and the risk for to bee brood) to bees following the use of 'Suxon Forest' (FR), 'Lotus Granuli', 'Suscon', and 'Merit Turf' from potential exposure to guttation fluid was identified.

The use of 'Suscon H&G' as a granule to flowers and ornamental plants was indicated in the GAP table to be used indoors only. The product 'Suscon' may also be used indoors. Low risk to pollinators was concluded for these products when they are used indoors.

4. Risk assessments for the metabolites

Based on the available information (see section 1.6, above) the plant metabolites have similar or lower toxicity to bees compared to the parent imidacloprid. Moreover, the level of residues measured in nectar or pollen of the olefine- and the monohydroxy-metabolites (the ones with similar toxicity to bees) was lower than that for the parent. Therefore, and also considering the conclusions of the risk assessment for the parent, no separate risk assessment was considered to be necessary.

5. Monitoring data

During the Pesticides Peer Review Experts' Meeting 97 monitoring data from Austria, Slovenia, Italy and France were presented.

5.1. Austrian monitoring project - MELISSA

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 objectives of the MELISSA project were: to document the incidences of honey bee losses in production areas of maize and oilseed rape; to analyse possible causes (honey bee pathogens and parasites, plant protection products); to evaluate the results with respect to measures taken to prevent honey bee losses; and to develop decision guidance for authorities, beekeepers and farmers for the implementation of measures to prevent honey bee losses by pathogens, parasites and plant protection products.

Diagnosis was performed for pathogens and parasites like *Varroa destructor*, *Nosema* spp., and several bee viruses. In addition, pesticide residue analyses in different bee matrices were performed for a variety of active substances including neonicotinoid seed treatments.

The results of the MELISSA project provided evidence that, in Austria, regional clustered bee damage had occurred in the years 2009 – 2011, which were frequently associated with the use of maize and oilseed pumpkin seeds coated with insecticides. It was noted that in some cases there was severe bee damage/colony losses yet no residues of the neonicotinoid pesticide active substances were detected. It was also noted that the presence of disease and combined stresses could have contributed or caused the colony damage. It was acknowledged that the residue analysis results would be diluted by samples from dead bees which had died from natural causes, therefore it is not surprising that residues greater than the LOQ were not detected. However, it was noted that monitoring data from Germany indicated detectable residue levels of neonicotinoids in dead bees where colony damage was observed.

The AT expert reported that regulatory measures (e.g. use of deflectors) to prevent honey bee losses possibly due to the exposure of bees to insecticidal seed dressing substances have significantly improved the situation. However, incidences of honey bee mortality observed repeatedly in defined regions suggest a systematic correlation with local factors contributing to the increased exposure of bees. The AT expert also noted that seed dressing quality and seed drilling equipment still need further improvement, and sowing of treated seed with pneumatic seed drillers should be avoided under windy conditions.

5.2. Incidences reported in Slovenia (2011)

The data presented at the meeting summarised reports on bee poisoning incidents in spring 2011 in the region of Pomurje (Slovenia, 2012). This report concerns thiametoxam and clothianidin rather than imidacloprid, but it is summarised here for completeness. The incidents concerned more than 2500 hives, representing nearly 10 % of the beekeepers in that region. Loss of worker bees and bee brood was reported by 41 beekeepers, and the majority of the beekeepers had bees foraging on flowering oilseed rape. The flowering oilseed rape had coincided with maize sowing.

A total of 42 samples were taken from dead bees, pollen, nectar, honey combs, flowering oilseed rape and maize seeds collected in the field, which were subsequently analysed for pesticide residues. A total of 19 samples of maize seeds treated with either 'Poncho' or 'Cruiser' from different commercial suppliers were analysed for dust abrasion (Heubach test). Furthermore, the following investigations were undertaken at farms within 3 km of the affected bee hives: land use, register and legitimacy of plant protection product use, accuracy of maize sowing equipment and spraying equipment, and declarations on maize seed. Further samples from other regions, where no bee poisoning incidents were reported, were taken from dead bees, pollen, oilseed rape and vegetables, and were subsequently analysed for pesticide residues.

The active substance clothianidin was most frequently found and was detected in 24 out of 51 samples, of which 12 were dead bee samples. The seed fulfilled prescribed national quality standards for dust abrasion that were introduced following bee poisoning incidents in 2008. Further records of bee poisoning in May and subsequent findings of clothianidin and thiamethoxam in dead bees can not be attributed to the sowing of maize as a route of exposure. Thiamethoxam was found in 4 samples, of which 2 were dead bee samples, but only after withdrawal of authorisation of ‘Cruiser’ for seed treatment. Several other active substances were detected in the samples of dead bees, pollen, nectar, fruit, oilseed rape and maize seeds. Although it was hypothesized that bees could have been exposed to dust generated during the maize sowing, further scientific investigations were envisaged by the Slovenian Authorities.

5.3. Monitoring in Italy

APENET monitoring network

Within the APENET project, a national monitoring network was established in 2009 - 2011, in order to gather information on the health status of the honeybee colonies. Hives situated in different geographic areas were monitored by means of periodic sampling and laboratory analysis on dead bees, live bees, brood, honey, wax and pollen. Monitoring data from the APENET network were considered in EFSA 2012c.

BEENET monitoring network

The project named "BeeNet-Beekeeping and networked environment" is a monitoring network and alert system to investigate Italian beekeeping problems, as well as to monitor abnormal events. This project is a follow-up of ‘APENET’ and represents the institutional monitoring activities for beekeeping need (Italy, 2012). The project started in 2011 and will end in June 2013. No further data are available.

5.4. Monitoring data from France

Targeted monitoring data for thiamethoxam (product ‘Cruiser’) from 2008 to 2010 in different regions of France were presented during the meeting. These data concern particularly thiamethoxam; these were summarised here only for completeness. The monitoring program included fields treated with thiamethoxam and control fields. Investigations for pathogens and parasites such as *Varroa* and *Nosema* spp., and residue analysis of thiamethoxam and clothianidin were performed.

The hives were maintained on-site so that they could potentially bee exposed to dust, guttation fluid and foraging on the flowering crop. Deflectors were introduced as mitigation measures in France in recent years. There were no effects which had been linked to exposure to thiamethoxam seed treatments. Some samples indicated detectable residues but these were not linked to adverse effects on the hive. It was noted to be problematic to conduct such dedicated and targeted monitoring. Some samples of thiamethoxam were detected in bee bread but this was prior to sowing and therefore could not be explained. Overall, there were no treatment-related bee losses over the 3-year monitoring period. It is acknowledged that this type of trial is difficult to conduct, nevertheless the FR expert believed that the results are useful to indicate no treatment related effects on bee hives.

5.5. Overall conclusion on the monitoring data

During the Pesticides Peer Review Experts' Meeting 97 the experts discussed the use of monitoring data for risk assessment. It was considered 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, environmental and agronomic conditions in the EU. Overall, it was considered that monitoring data are of limited use for risk assessment but may be useful to provide feedback for risk managers to consider prevention measures.

6. List of data gaps identified during the assessment

- Further information to address the risk to pollinators other than honey bees (relevant for all outdoor uses evaluated, including uses when the plants or soil substrates are treated indoor, but the plants are planted out or the substrates are used outdoor at a later stage; see section on 'Conclusions of the evaluation').

- Further assessment of the risk to honey bees foraging in nectar and/or pollen in succeeding crops (relevant for all outdoor uses evaluated, including uses when the plants or soil substrates are treated indoor, but the plants with the substrate are planted out at a later stage; see section on 'Conclusions of the evaluation').

- Further information to address the risk to honey bees foraging on insect honey dew (relevant for all outdoor uses evaluated, including uses when the plants or soil substrates are treated indoor, but the plants are planted out or the substrates are used outdoor at a later stage; see section 2.2).

<u>Formulations for seed dressing:</u>

- To further address the potential <u>dust</u> exposure, and hence the risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood). The data gap is relevant for all the uses evaluated except for beet crops such as sugar beet, fodder beet, mangolds; see section 2.1.

- To further address the risk following the <u>ingestion of contaminated nectar and/or pollen</u> (i.e. the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk following exposure to sublethal doses) in asparagus, pumpkin, linseed, cotton, sunflower, oilseed rape and maize. Essential information (levels of residues in nectar and pollen) were missing for a first-tier risk assessments for asparagus, pumpkin and linseed. It is noted that for maize a considerable margin of safety was evaluated at the first-tier risk assessments for adult bees (however no assessments for brood were available). The assessments using a sublethal endpoint also indicated a margin of safety for cotton, sunflower, oilseed rape and maize. See section 2.2.

- To further address the potential exposure via <u>guttation</u> fluid, and hence the risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood). The data gap is relevant for all authorised uses evaluated; see section 2.3.

<u>Granular formulations:</u>

- To further address the potential <u>dust</u> exposure, and hence the risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood) following the use of the products 'Merit Turf', 'Lotus Granuli' and 'Suscon'. The data gap is relevant for the uses when the product is blended with the soil substrate using machinery outdoors; see section 3.1.

- To further address the risk following the <u>ingestion of contaminated nectar and/or pollen</u> (i.e. the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk following exposure to sublethal doses) for the use of the products 'Suscon' and 'Lotus Granuli'. The data gap is relevant for the uses in ornamental plants and flowers outdoors; see section 3.2.

- To further address the risk following the <u>ingestion of contaminated nectar and/or pollen</u> of flowering weeds (which may occur in the treated area), i.e. the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk following exposure to sublethal doses for the use of the products 'Merit Turf' and 'Lotus

Granuli'. The data gap is relevant for the uses in amenity turf, turf, public grass vegetation and home garden lawns; see section 3.2.

- To further address the potential exposure via guttation fluid and hence the risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood) following the use of the products 'Suxon Forest', 'Suscon', 'Merit Turf' and 'Lotus Granuli'. The data gap is relevant for all the outdoor uses evaluated for these products including uses when the plants or soil substrates are treated indoor, but the plants are planted out or the substrates are used outdoor at a later stage; see section 3.3.

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

- None

8. Concerns

8.1. 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 to pollinators other than honey bees, the risk from residues in insect honey dew, and the risk from exposure to residues in succeeding crops could not be finalised.

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 9.

8.2. Critical areas of concern

A high acute risk to honey bees was identified from exposure via dust drift for the authorised uses in cereals, cotton, maize and oilseed rape. A high acute risk was also identified for exposure via residues in nectar and/or pollen for the authorised uses in cotton, oilseed rape and sunflowers.

The risks identified are marked with an 'R' in the overview table in section 9. Risks have been identified where either a 1st tier risk assessment indicated a high risk (not including the screening step assessment for exposure via dust and guttation), or a higher tier study indicated a high risk.

9. Overview of the concerns identified for the authorised uses of imidacloprid

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 1[st] 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 State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
asparagus	Gaucho WS (004787-00)	DE	147.42	X	X	X	X	X	X	X	X	X	X
bulb crops	Gaucho WS (004787-00)	DE	182.7	X	X	X[a]	X[a]	X[a]	X	X	X	X	X
cereals: wheat /barley/oat	Gaucho 600 FS	AT	72	R	X				X	X	X	X	X
	Escocet	ES	140	R	X				X	X	X	X	X
	Gaucho 350	FR	126	R	X				X	X	X	X	X
	Gaucho 350	FR	112	R	X				X	X	X	X	X
	Yunta Quattro	HU	100	R	X				X	X	X	X	X
	Nuprid 600 FS	IT	Not available	R	X				X	X	X	X	X
	Astep 225 FS	PL	63	R	X				X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
cereals: wheat /barley/oat	Astep 225 FS	PL	87.5	R	X				X	X	X	X	X
	Nuprid Max 222 FS	PL	157.5	R	X				X	X	X	X	X
	Tripod Plus	UK	70.2	R	X				X	X	X	X	X
cotton	GAUCHO 350 FS	EL	100	R	X	X	R	X	X	X	X	X	X
	GAUCHO 600 FS	EL	100	R	X	X	R	X	X	X	X	X	X
	GAUCHO 70 WS	EL	100	R	X	X	R	X	X	X	X	X	X
	SEEDOPRID 600 FS	EL	100	R	X	X	R	X	X	X	X	X	X
	NUPRID 600 FS	EL	100	R	X	X	R	X	X	X	X	X	X
flowers, ornamentals	Lotus granuli**	IT	Not available	X	X	X	X	X	X	X	X	X	X
	Suscon**	IT	Not available	X[b]	X[b]	X[b]	X[b]	X[b]	X[b]	X[b]	X[b]	X[b]	X[b]
	Suscon H&G**	IT	Not available										
forestry / nurseries / container-	Suxon forest**[c]	FR	Not relevant										

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
grown forest trees/forest tree seedlings	Suxon forest**	FR	500						X	X	X	X	
headed brassicas / leafy brassicas broccoli / cauliflower /kohlrabi / head cabbage / Brussels sprout / Chinese cabbage / kale	Gaucho WS (004787-00)	DE	147.42	X	X				X	X	X	X	X
	Gaucho WS (004787-00)	DE	147.42	X	X				X	X	X	X	X
	Gaucho WS (004787-00)	DE	147.42	X	X				X	X	X	X	X
	Gaucho WS (004787-00)	DE	147.42	X	X				X	X	X	X	X
	Gaucho Tuinbow 12341	NL	90.3	X	X				X	X	X	X	X
leek	Gaucho WS (004787-00)	DE	90.3	X	X				X	X	X	X	X
	Gaucho Tuinbouw 12341	NL	67.2	X	X				X	X	X	X	X
	Gaucho Tuinbouw 12341	NL	60.5	X	X				X	X	X	X	X
lettuce / endive /radicchio rosso / sugar loaf	Gaucho 70 WS	BE	Not available	X	X				X	X	X	X	X
	Gaucho WS (004787-00)	DE	145.6	X	X				X	X	X	X	X
	Gaucho Tuinbouw 12341	NL	108	X	X				X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
lettuce / endive /radicchio rosso / sugar loaf	Gaucho Tuinbouw 12341	NL	120	X	X				X	X	X	X	X
linseed	Chinook 200 FS	CZ	17.1	X	X	X	X	X	X	X	X	X	X
	Chinook (004672-00)	DE	10	X	X	X	X	X	X	X	X	X	X
maize / corn /fodder maize / sugar maize	Gaucho 600 FS	AT	108	R	X	X	X	X	X	X	X	X	X
	Gaucho R 70 WS	BE	160	R	X	X	X	X	X	X	X	X	X
	GAUCHO 350 FS	EL	100	R	X	X	X	X	X	X	X	X	X
	GAUCHO 600 FS	EL	100	R	X	X	X	X	X	X	X	X	X
	GAUCHO 70 WS	EL	100	R	X	X	X	X	X	X	X	X	X
	SEEDOPRID 600FS	EL	100	R	X	X	X	X	X	X	X	X	X
	NUPRID 600 FS	EL	100	R	X	X	X	X	X	X	X	X	X
	Nuprid	EE	108	R	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
maize / corn /fodder maize / sugar maize	Escocet,Picus 35/ Seedoprid 350 FS	ES	157.5	R	X	X	X	X	X	X	X	X	X
	Seedoprid red, Seedoprid 600 FS	ES	108	R	X	X	X	X	X	X	X	X	X
	Gaucho 600 FS	HU	67.5	R	X	X	X	X	X	X	X	X	X
	Gaucho 350 FS	IT	90	R	X	X	X	X	X	X	X	X	X
	Nuprid 350 FS	IT	Not available	R	X	X	X	X	X	X	X	X	X
	Nuprid 600 FS Blanco	IT	Not available	R	X	X	X	X	X	X	X	X	X
	Nuprid 600 FS	IT	Not available	R	X	X	X	X	X	X	X	X	X
	Nuprid 600 FS	PL	108	R	X	X	X	X	X	X	X	X	X
	Couraze 350 FS	PL	267.75	R	X	X	X	X	X	X	X	X	X
	Gaucho 600 FS	PL	162	R	X	X	X	X	X	X	X	X	X
	Gaucho	PT	181.79	R	X	X	X	X	X	X	X	X	X
	Gaucho 600 FS	SK	54	R	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
onion	Gaucho 600 FS	AT	450 (?)	X	X				X	X	X	X	X
	Gaucho WS (004787-00)	DE	179.9	X	X				X	X	X	X	X
potato	Gaucho 600 FS	AT	180	X	X				X	X	X	X	X
	Monceren G	CZ	180	X	X				X	X	X	X	X
	Prestive FS 370	DK	72	X	X				X	X	X	X	X
	Monceren G	EE	145	X	X				X	X	X	X	X
	Escocet,Picus 35/ Seedoprid 350 FS	ES	280	X	X				X	X	X	X	X
	Escocet,Picus 35/ Seedoprid 350 FS	ES	1120	X	X				X	X	X	X	X
	Prestige 290 FS	HU	350	X	X				X	X	X	X	X
	Nuprid 600 FS Blanco	IT	Not available	X	X				X	X	X	X	X
	Nuprid 600 FS	IT	Not available	X	X				X	X	X	X	X
	Monceren G	LT	216	X	X				X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
potato	Prestige Forte 370 FS	PL	468	X	X				X	X	X	X	X
	Gaucho	PT	75	X	X				X	X	X	X	X
	Prestige 290 FS	SK	560	X	X				X	X	X	X	X
pumpkin seeds	Gaucho 600 FS	AT	20.52	X	X	X	X	X	X	X	X	X	X
oilseed rape	Chinook	AT	10.01	R	X	X	R	X	X	X	X	X	X
	Antarc (004674-00)	DE	52.5	R	X	X	R	X	X	X	X	X	X
	Chinook (004672-00)	DE	10	R	X	X	R	X	X	X	X	X	X
	Nuprid	EE	20	R	X	X	R	X	X	X	X	X	X
	Chinook FS 200	FIN	16	R	X	X	R	X	X	X	X	X	X
	Chinook 200 FS	HU	16	R	X	X	R	X	X	X	X	X	X
	Chinook/Chinook Blue 200 FS	PL	10	R	X	X	R	X	X	X	X	X	X
	Couraze 350 FS	PL	39.2	R	X	X	R	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
oilseed rape	Nuprid 600 FS	PL	12.24	R	X	X	R	X	X	X	X	X	X
	Chinook 200 FS	SE	10	R	X	X	R	X	X	X	X	X	X
	Chinook 200 FS	SK	10	R	X	X	R	X	X	X	X	X	X
	Chinook	UK	12	R	X	X	R	X	X	X	X	X	X
sugar beet / fodder beet / beet /mangolds	Gaucho 600 FS ungefärbt	AT	90						X	X	X	X	X
	Gaucho 70 WS	CZ	117						X	X	X	X	X
	Gaucho70WS/ Gaucho R 70 WS	BE	109						X	X	X	X	X
	Gaucho WS (004787-00)	DE	118.3						X	X	X	X	X
	Imprimo (004680-00)	DE	117						X	X	X	X	X
	Traffic (004681-00)	DE	78						X	X	X	X	X
	Gaucho WS 70	DK	66						X	X	X	X	X
	Nuprid	EE	108						X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
sugar beet / fodder beet / beet /mangolds	GAUCHO 350 FS	EL	100						X	X	X	X	X
	GAUCHO 600 FS	EL	100						X	X	X	X	X
	GAUCHO 70 WS	EL	100						X	X	X	X	X
	SEEDOPRID 600FS	EL	100						X	X	X	X	X
	NUPRID 600 FS	EL	100						X	X	X	X	X
	Gaucho 70 WS, Seedo	ES	163.8						X	X	X	X	X
	Seedoprid red, Seedoprid 600 FS	ES	162						X	X	X	X	X
	Gaucho WS 70	FIN	60						X	X	X	X	X
	Gaucho 600 FS	FR	127						X	X	X	X	X
	Gaucho 70 WS	FR	127						X	X	X	X	X
	Imprimo	FR	126						X	X	X	X	X
	Nuprid 70	FR	126						X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
sugar beet / fodder beet / beet /mangolds	Gaucho 600 FS	HU	90						X	X	X	X	X
	Gaucho	IE	100						X	X	X	X	X
	Gaucho 70 WS	IT	Not available						X	X	X	X	X
	Gaucho	NL	91						X	X	X	X	X
	Sombrero	NL	90						X	X	X	X	X
	Montur Forte 230 FS	PL	18						X	X	X	X	X
	Nuprid 600 FS	PL	111.6						X	X	X	X	X
	Gaucho 70 WS	SE	60						X	X	X	X	X
	Gaucho	UK	91						X	X	X	X	X
sunflower	Gaucho 600 FS	HU	35	X	X	X	R	X	X	X	X	X	X
home garden lawn / public grass vegetation /	Lotus granuli**	IT	125	X	X	X[d]	X[d]	X[d]	X	X	X	X	X

Crop/Situation	Product Name	Member State	’Maximum application rate’ g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk from sublethal exposure to honey bees	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
amenity turf (golf courses, sport grounds, commercial and residential lawns,…)	Merit Turf**	NL	150	X	X	X[d]	X[d]	X[d]	X	X	X	X	X
	Merit Turf**	NL	150	X	X	X[d]	X[d]	X[d]	X	X	X	X	X
	Merit Turf**	SE	150	X	X	X[d]	X[d]	X[d]	X	X	X	X	X

Table compiled on the basis of Appendix A.
** applied as granules
a: only in the case of flowering bulbs
b: the assessments are considered to be finalised (and low risk was concluded) when the product is used indoors
c: it was assumed that the plants are kept indoors
d: Potential exposure to honey bees from residues in nectar and pollen in flowering weeds

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APPENDICES

APPENDIX A – IMIDACLOPRID: SUMMARY OF AUTHORISED USES FOR SEED TREATMENT AND GRANULES

Crop/Situation	Product Name	Application rate per treatment				
		Member State	g a.s/.ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
asparagus	Gaucho WS (004787-00)	DE		147.42	2.34 ml/ 1000 seeds	90 000 seeds/ha
bulb crops	Gaucho WS (004787-00)	DE		182.7	29 ml/ seedunit*	max. 9 seedunits*/ha
cereals: (winter) wheat / (winter) barley / oat	Gaucho 600 FS	AT		72		
	Escocet	ES	-	140	70 g a.s./100 kg seeds	200 kg seeds/ha
	Gaucho 350	FR		126	70 g a.s./100 kg seeds	180 kg seeds /ha
	Gaucho 350	FR		112	70 g a.s./100 kg seeds	160 kg seeds /ha
	Yunta Quattro	HU	45	100	30-33.34 g /100 kg seeds	150-300 kg seeds/ha
	Nuprid 600 FS	IT		Not available data	0.072 kg/100 kg seeds	
	Astep 225 FS	PL	49	63	35 g a.s./100 kg seeds	140-180 kg seeds/ha
	Astep 225 FS	PL	52.5	87.5	35 g a.s./100 kg seeds	150- 250 kg seeds/ha
	Nuprid Max 222 FS	PL	78.75	157.5	52.5 g a.s./100 kg seeds	150-300 kg/ha
	Tripod Plus	UK		70.2	35.1 g / 100 kg seeds	200 kg / ha
cotton	GAUCHO 350 FS	EL	75	100	525-700 ml/100 kg seeds	
	GAUCHO 600 FS	EL	75	100	540-700 ml/100 kg seeds	
	GAUCHO 70 WS	EL	75	100	525-700 ml/100 kg seeds	
	SEEDOPRID 600 FS	EL	75	100	540-700 ml/100 kg seeds	
	NUPRID 600 FS	EL	75	100	540-700 ml/100 kg seeds	
flowers, ornamentals	Lotus granuli**	IT		Not available data		
	Suscon, Suscon H&G**	IT		Not available data		

Crop/Situation	Product Name	Application rate per treatment				
		Member State	g a.s/.ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
forestry / nurseries / container-grown forest trees / forest tree seedlings	Suxon forest**	FR	Not relevant	Not relevant	Not concerned	Not concerned
	Suxon forest**	FR	250	500	Not concerned	Not concerned
headed brassicas / leafy brassicas / broccoli / cauliflower / kohlrabi / head cabbage / Brussels sprout / Chinese cabbage / kale	Gaucho WS (004787-00)	DE		147.42	2.34 ml/ 1000 seeds	90.000 seeds/ha
	Gaucho WS (004787-00)	DE		147.42	2.34 ml/ 1000 seeds	90.000 seeds/ha
	Gaucho WS (004787-00)	DE		147.42	2.34 ml/ 1000 seeds	90.000 seeds/ha
	Gaucho WS (004787-00)	DE		147.42	2.34 ml/ 1000 seeds	90.000 seeds/ha
	Gaucho Tuinbow 12341	NL		90.3	1.51 mg a.s./seed	n/a (seeds sown indoors) 60 000 plants/ha
leek	Gaucho WS (004787-00)	DE		90.3	64.3 ml/ seedunit*	max. 2 seedunits*/ha
	Gaucho Tuinbouw 12341	NL		67.2	0.224 mg a.s./seed	n/a (seeds sown indoors) 300 000 plants/ha
	Gaucho Tuinbouw 12341	NL		60.5	0.224 mg a.s./seed	270 000 seeds/ha
lettuce / endive / radicchio rosso / sugar loaf	Gaucho 70 WS	BE		Not available data	80 g/100 000 seeds	
	Gaucho WS (004787-00)	DE		145.6	1.04 ml/ 1000 seeds	200.000 seeds/ha
	Gaucho Tuinbouw 12341	NL	80	108	0.81 mg a.s./seed	n/a (seeds sown indoors) 100 000-135 000 plants/ha
	Gaucho Tuinbouw 12341	NL	120	120	1.2 mg a.s./seed	n/a (seeds sown indoors) 100 000 plants/ha
linseed	Chinook 200 FS	CZ	14.82	17.1	1.3-1.5 l/ t seed	max. 114 kg seeds/ha
	Chinook (004672-00)	DE		10	3 ml/ kg seed	max. 33 kg seeds/ha

Crop/Situation	Product Name	Application rate per treatment				
		Member State	g a.s/.ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
maize / corn / fodder maize / sugar maize	Gaucho 600 FS	AT		108		
	Gaucho R 70 WS	BE		160	80 g/50 000 seeds	
	GAUCHO 350 FS	EL	75	100	500-700 ml/100 kg seeds	
	GAUCHO 600 FS	EL	75	100	780-1200 ml/unit* seed	
	GAUCHO 70 WS	EL	75	100	770-1200 ml/unit* seed	
	SEEDOPRID 600FS	EL	75	100	780-1200 ml/unit* seed	
	NUPRID 600 FS	EL	75	100	780-1200 ml/unit* seed	
	Nuprid	EE	90	108	108 g a.s./100 000 seeds	
	Escocet, Picus 35 FS, Seedoprid 350 FS	ES	78.5	157.5	350-525 g a.s./100 kg seeds	75 000-100 000 seeds/ha
	Seedoprid red, Seedoprid 600 FS	ES	81	108	54 g a.s./50 000 seeds	75 000-100 000 seeds/ha
	Gaucho 600 FS	HU	52.5	67.5	67.5 g /50 000 seeds	50 000 seeds/ha
	Gaucho 350 FS	IT	60	90		
	Nuprid 350 FS	IT		Not available data	0.35-0.7 kg/100 kg seeds	
	Nuprid 600 FS Blanco	IT		Not available data	0.36-0.72 kg/100 kg seeds	
	Nuprid 600 FS	IT		Not available data	0.36-0.72 kg/100 kg seeds	
	Nuprid 600 FS	PL	75.6	108	54 g /50 000 seeds	70 000-100 000 seeds/ha
	Couraze 350 FS	PL		267.75	3.85 g - 5.95 g/1 kg seeds	max. 45 kg/ha
	Gaucho 600 FS	PL		162	3.0-3.6 g /1 kg seeds	max. 45 kg/ha
	Gaucho	PT		181.79	1.2	75 000 to 95 0000 seeds/ha
	Gaucho 600 FS	SK		54	54 g a.s./unit*	

Crop/Situation	Product Name	Application rate per treatment				
		Member State	g a.s/.ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
onion	Gaucho 600 FS	AT		450 (?)		
	Gaucho WS (004787-00)	DE		179.9	64.3 ml/ seedunit*	max. 4 seedunits*/ha
potato	Gaucho 600 FS	AT		180		
	Monceren G	CZ		180	0.072 kg a.s./t	max. 2.5 t potato seeds/ha
	Prestive FS 370	DK		72	7.2 g a.s./100 kg potatoes	
	Monceren G	EE		145	72 g a.s./t potatoes	
	Escocet, Picus 35 FS, Seedoprid 350 FS	ES	120	280	12-14 g a.s./100 kg seeds	1000-2000 kg seeds/ha
	Escocet, Picus 35 FS, Seedoprid 350 FS	ES	120	1120	12-56 g a.s./100 kg seeds	1000-2000 kg seeds/ha
	Prestige 290 FS	HU		350	10-17.5 g/100 kg tuber	2000-3500 kg tuber/ha
	Nuprid 600 FS Blanco	IT		Not available data	0.015-0.024 kg/100 kg seeds	
	Nuprid 600 FS	IT		Not available data	0.015-0.024 kg/100 kg seeds	
	Monceren G	LT	180	216	0.072 kg a.s./t	2.5-3 t potato seeds/ha
	Prestige Forte 370 FS	PL	86.4	468	7.2 g a.s./100 kg	1.2-6.5 t of potato tubers/ha
	Gaucho	PT		75		2 t potato seeds/ha
	Prestige 290 FS	SK		560	14 g a.s./100 kg	4t seeds/ha
pumpkin seeds	Gaucho 600 FS	AT		20.52		
oilseed rape	Chinook	AT		10.01		
	Antarc (004674-00)	DE		52.5	25 ml/ kg seed	max. 5 kg seeds/ha
	Chinook (004672-00)	DE		10	20 ml/ kg seed	max. 5 kg seeds/ha
	Nuprid	EE		20	2 kg a.s./t seed	
	Chinook FS 200	FIN	6	16		
	Chinook 200 FS	HU	12	16	200 g /100 kg seeds	6-8 kg seeds/ha
	Chinook 200 FS, Chinook Blue 200 FS	PL	-	10	2 g/1 kg seeds	2.5-5 kg seeds/ha

Crop/Situation	Product Name	Application rate per treatment				
		Member State	g a.s/.ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
oil seed rape	Couraze 350 FS	PL		39.2	4.9 g/1 kg seeds	2.5-8 kg/ha
	Nuprid 600 FS	PL	8.16	12.24	2.04 g /1 kg seeds	4-6 kg/ha
	Chinook 200 FS	SE		10	0.02 l product/kg seeds	5.0 kg/ha
	Chinook 200 FS	SK		10	200 g a.s./100 kg	5 kg seeds/ha
	Chinook	UK		12	200 g a.s. / 100 kg seeds	6 kg / ha
sugar beet / fodder beet / beet / mangolds	Gaucho 600 FS ungefärbt	AT		90		
	Gaucho 70 WS	CZ		117	90 g a.s./unit (100 000 seeds per unit)	1.3 unit/ha (100 000 seeds per unit)
	Gaucho 70 WS/Gaucho R 70 WS	BE		109	91 g/ 100 000 seeds	
	Gaucho WS (004787-00)	DE		118.3	130 ml/ seedunit*	max. 1.3 seedunits*/ha
	Imprimo (004680-00)	DE		117	225 ml/ seedunit*	max. 1.3 seedunits*/ha
	Traffic (004681-00)	DE		78	150 ml/ seedunit*	max. 1.3 seedunits*/ha
	Gaucho WS 70	DK		66	0.06 kg a.s./100 000 seeds	
	Nuprid	EE	90	108	108 g a.s./100 000 seeds	
	GAUCHO 350 FS	EL	75	100	59.5 - 70 ml/unit* seed	
	GAUCHO 600 FS	EL	75	100	60-90 ml/unit* seed	
	GAUCHO 70 WS	EL	75	100	60-90 ml/unit* seed	
	SEEDOPRID 600FS	EL	75	100	60-90 ml/unit* seed	
	NUPRID 600 FS	EL	75	100	60-90 ml/unit* seed	
	Gaucho 70 WS, Seedo	ES	109.2	163.8	91 g a.s./100 000 seeds	120 000-180 000 seeds/ha
	Seedoprid red, Seedoprid 600 FS	ES	108	162	90 g a.s./100 000 seeds	120 000-180 000 seeds/ha
	Gaucho WS 70	FIN		60		1.0 unit (10000 seeds)/ha
	Gaucho 600 FS	FR		127	90 g a.s./unit (100 000 seeds per unit)	1.4 unit/ha (100 000 seeds per unit)
	Gaucho 70 WS	FR		127	90 g a.s./unit (100 000 seeds per unit)	1.4 unit/ha (100 000 seeds per unit)
	Imprimo	FR		126	90 g a.s./unit (100 000 seeds per unit)	1.4 unit/ha (100 000 seeds per unit)

Crop/Situation	**Product Name**	**Application rate per treatment**				
		Member State	**g a.s/.ha min**	**g a.s./ha max**	**Seed dressing rate**	**Seed drilling rate (seed density rate)**
sugar beet / fodder beet / beet / mangolds	Nuprid 70	FR		126	90 g a.s./unit (100 000 seeds per unit)	1.4 unit/ha (100 000 seeds per unit)
	Gaucho 600 FS	HU		90	90 g /100 000 seeds	100 000 seeds/ha
	Gaucho	IE	82	100	130 g /100 000 seeds	100 000 seeds/ha (+/- 10%)
	Gaucho 70 WS	IT		Not available data		1.5 unit/ha (1 unit = 100 000 seeds)
	Gaucho	NL		91	0.91 mg a.s./seed	100 000 seeds/ha
	Sombrero	NL	72	90	0.90 mg a.s./seed	80 000-100 000 seeds/ha
	Montur Forte 230 FS	PL		18	15 g a.s./100 000 seeds	120 000 seeds/ha
	Nuprid 600 FS	PL	95.4	111.6	90 g /100 000 seeds	106 000 - 124 000 seeds/ha
	Gaucho 70 WS	SE		60	0.085 kg product/100 000 seeds	100 000 seeds/ha
	Gaucho	UK		91	91 g / 100 000 seeds	100 000 seeds / ha
sunflower	Gaucho 600 FS	HU	24	35	105 g / 150 000 seeds	50 000 seeds/ha
home garden lawn / public grass vegetation / amenity turf (golf courses, sport grounds, commercial and residential lawns,…)	Lotus granuli**	IT		125		
	Merit Turf**	NL		150		
	Merit Turf**	NL		150		
	Merit Turf**	SE		150		30 kg/ha

Table compiled based on Member States` feedback provided during a consultation via a written procedure in September 2012. Note: not all the 27 Member States provided feedback.
* The amount of seeds in the unit is not available
** applied as granules

ABBREVIATIONS

µg	microgram
a.s.	active substance
AF	assessment factor
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
d	day
DAR	Draft Assessment Report
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)
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
g	gram
GAP	good agricultural practice
GM	geometric mean
GS	growth stage
h	hour(s)
ha	hectare
L	litre
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
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
OM	organic matter content
Pa	Pascal
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
PER	proboscis extension reflex
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
ppb	parts per billion (10^{-9})
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SL	soluble (liquid) concentrate
SSD	species sensitivity distribution
$t_{1/2}$	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