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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 clothianidin[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

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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 clothianidin, as regards the risk to bees. In this context the conclusions of EFSA concerning the risk assessment for bees for the active substance clothianidin 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 clothianidin 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.

KEY WORDS

Clothianidin, peer review, risk assessment, pesticide, insecticide

[1] On request from the European Commission, Question No EFSA-Q-2012-00793, approved on 19 December 2012.

[2] Correspondence: pesticides.peerreview@efsa.europa.eu

[3] On page 31 of the Conclusion the unit is changed from “mg a.s./100 kg granules” to “g a.s./100 kg granules” following an error reported by the applicant (Sumitomo Chemical Agro Europe) occurred in the unit for the conversion of the absolute residues of clothianidin into the amount per granules given in the study report Lindner, 2009 (study 34). The risk assessment remained unchanged.

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SUMMARY

Clothianidin was included in Annex I to Directive 91/414/EEC on 1 August 2006 by Commission Directive 2006/41/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 clothianidin, 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 clothianidin 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 treatment 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 finalised on the basis of the available information. A high risk was indicated or could not be excluded in relation to certain aspects of the risk assessment for honey bees for some of the authorised uses. For some exposure routes it was possible to identify a low risk for some of the authorised uses.

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BACKGROUND

Clothianidin was included in Annex I to Directive 91/414/EEC[4] on 1 August 2006 by Commission Directive 2006/41/EC[5], and has been deemed to be approved under Regulation (EC) No 1107/2009[6], in accordance with Commission Implementing Regulation (EU) No 540/2011[7], as amended by Commission Implementing Regulation (EU) No 541/2011[8]. The peer review leading to the approval of this active substance was finalised in 2006, and the EFSA has not been previously involved in the evaluation of this active substance.

The specific provisions of the approval were amended by Commission Directive 2010/21/EU[9], 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 clothianidin, 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 as the specific issues raised by Member States following the consultation were discussed at the

[4] 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 2006/41/EC of 7 July 2006 amending Council Directive 91/414/EEC to include clothianidin and pethoxamid as active substances. OJ L 187, 8.7.2006, p. 24-27.

[6] 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.

[7] 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.

[8] 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.

[9] 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.

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 clothianidin authorised as seed treatments or granules on a variety of crops in Europe. In addition to the available EU evaluations, 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[10],
- the report of the scientific consultation with Member State experts,
- the comments received on the draft EFSA conclusion.

[10] 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 some Member States 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 via dust drift. The risk to pollinators other than honey bees should be further considered. A data gap is therefore concluded for further information to address the risk to pollinators (other than honey bees).

Exposure to succeeding crop residues in nectar and pollen or guttation fluid could represent a concern and should be further considered. For clothianidin, limited residue data in pollen and nectar for succeeding crops were available but the analysis indicated residue levels below the LOQ. However, as the data set is limited, a data gap is 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 treated seed. However, potential uptake via roots to flowering weeds cannot be excluded for the uses as granules. Therefore a data gap is identified to further address this issue.

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 crops 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: section 3).

1. Toxicity endpoints

The acute toxicity endpoints for clothianidin were derived from the list of endpoints in the review report (European Commission, 2005) and the DAR (Belgium, 2003).

Some other data which were available in the dossier submitted by the applicant for the national authorisation of the plant protection products were also considered as relevant for the risk assessment. In particular, a 10-day chronic effect test on honey bee (Kling, A., 2005, **study 31;** see Study evaluation notes; EFSA 2012d) and a study investigating exposure to spiked diet on honey bee larvae (Maus, Ch., 2009, **study 32;** see Study evaluation notes; EFSA 2012d). In the test by Kling, A., 2005, the chronic effects of clothianidin on the honey bee, *Apis mellifera L.*, were determined in a 10-day continuous feeding test in the laboratory. The NOEC value was determined at the end of the test period. Bees were exposed to 50 % sugar solution containing four different concentrations of the test item clothianidin by continuous and *ad libitum* feeding over a period of 10 days. Mortality was recorded every day.

In the study by Maus, Ch., 2009, the effects of clothianidin on honey bee larvae *(Apis mellifera carnica)* after artificial feeding of spiked diet in an *in vitro* laboratory testing design were investigated. Bee larvae were fed with standardised amounts of artificial diet. The test item was incorporated into the artificial food at different concentrations within an appropriate range in order to determine the NOEC. Based on the statistical significance of the effects observed on mortality up to day 22 in three valid test runs, it was concluded that the **NOEC values for this study were 20 and 40 µg a.s./kg diet**. Thus, the LOEC is determined to be ≥ 40 µg a.s./kg diet.

A summary of the toxicity endpoints considered is reported in Table 1.

Table 1: Toxicity endpoints for clothianidin

Toxicity endpoints		Species	Reference
Acute oral toxicity LD_{50} (NOEL) µg a.s/bee	**0.00379** (0.001024)	*Apis mellifera*	European Commission, 2005
Acute contact toxicity LD_{50} (NOEL) µg a.s./bee	0.04426 (0.008) **0.0275***	*Apis mellifera*	European Commission, 2005 European Commission, 2006*
Chronic toxicity 10-day NOEC µg a.s./L	**10**	*Apis mellifera*	Kling, A., 2005, study 31; see Study evaluation notes; EFSA 2012d
Honey bee larvae NOEC µg a.s./kg diet	**20** and 40	*Apis mellifera*	Maus, Ch., 2009, study 32; see Study evaluation notes; EFSA 2012d

Value in **bold** used for risk assessment

*An acute contact LD_{50} value for clothianidin as a metabolite of thiamethoxam as presented in the Review Report (European Commission, 2006).

No sublethal endpoints were available in the dossiers from the applicant, but in Schneider *et al.* 2012, following the investigation of sublethal doses of imidacloprid and clothianidin effects on the foraging behaviour were observed at **0.5 ng/bee** (single oral treatment via sucrose solution a few hours before the first observation). This dose was used for the risk assessment with clothianidin.

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

Screening step

A quantitative risk assessment was not available and currently no agreed guidance or trigger value is available to assess the risk to honey bees from dust drift. However, Appendix J of EFSA, 2012a suggests to use the full dose (active substance application rate in terms of g a.s/ha) as a very worst case screening step. The assessments considering the whole in-field application rate for the highest and lowest 'maximum application rates' authorised in the EU (see Appendix A), are illustrated in Table 2, below.

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

	Application rate (g a.s./ha) [1]	**HQ_{oral} (LD_{50} 0.00379 µg a.s. /bee)**	**$HQ_{contact}$ (LD_{50} 0.0275 µg a.s. /bee)**
lowest 'maximum application rate' (poppy)	7.02	1852	225
highest 'maximum application rate' (maize)	125	32982	4545

[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).

The resulting HQ values are high (i.e. greater than the current trigger of 50 for foliar spray risk assessment) and therefore the screening risk assessment is not sufficient to indicate a low risk.

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

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'[11] would be useful. It should be noted that the deposition values from the SANCO/10553/2012 guidance were also considered within the draft EFSA guidance document for bees[12] (under development at the time of this evaluation) and were amended by taking into account landscape factors when contamination of nectar and pollen is estimated (i.e. by considering the oral exposure). The default deposition values for adjacent crops proposed are approximately 50 % of those used in the risk assessments presented in Table 3.

In the following risk assessments for maize, oilseed rape, cereals and sugar beet uses the proposed default deposition values to adjacent vegetation were used. The assessment is based on the highest

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

[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).

and lowest 'maximum application rates' authorised in the EU for each of these uses and on the acute oral and acute contact LD_{50} values which were used in the screening assessment (Table 2). Table 3 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 3: Tier 1 HQ values calculated using the proposed default deposition values in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012' for the highest and lowest '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)	25	125
	% deposition (adjacent vegetation)	7	7
	Predicted off-field deposition rate (g a.s./ha)	1.75	8.75
	Acute oral HQ[2]	461.7	2308.7
	Acute contact HQ[3]	63.6	318.2
Oilseed rape	Application rate (g a.s./ha)	25	80
	% deposition (adjacent vegetation)	2.7	2.7
	Predicted off-field deposition rate (g a.s./ha)	0.675	2.16
	Acute oral HQ[2]	178.1	569.9
	Acute contact HQ[3]	24.5	78.5
Cereals	Application rate (g a.s./ha)	58.68	110
	% deposition (adjacent vegetation)	4.1	4.1
	Predicted off-field deposition rate (g a.s./ha)	2.40588	4.51
	Acute oral HQ[2]	634.8	1190.0
	Acute contact HQ[3]	87.5	164
Sugar beet	Application rate (g a.s./ha)	10	108
	% deposition (adjacent vegetation)	0.01	0.01
	Predicted off-field deposition rate (g a.s./ha)	0.001	0.0108
	Acute oral HQ[2]	0.26	2.85
	Acute contact HQ[3]	0.04	0.39

[2] Calculated using an acute oral LD_{50} of 0.00379 µg a.s./bee (see Table 1)
[3] Calculated using an acute contact LD_{50} of 0.0275 µg a.s./bee (see Table 1)

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

As indicated in Table 3, 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, and therefore a higher tier risk assessment is required (see section 2.1.4).

The resulting tier 1 HQ values for sugar beet for both oral and contact exposure are low 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 clearly sufficient to demonstrate low acute risk to honey bees for sugar beet.

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 10-day LC_{50} value. This assessment would cover the potential chronic effects. To conduct such calculations, the uptake rate of a bee should be estimated after foraging on crops exposed to dust drift. Residue levels in nectar and pollen that may occur after such exposure are not available and currently no official guidance is available for these estimations. Therefore, the first-tier chronic risk assessment for the situations when bees forage on a crop exposed to dust drift emitted during the drilling procedure cannot be performed. If data on the residues in nectar and pollen would be available, based on this information and on the daily nectar and pollen consumption of bees, the daily uptake of clothianidin could be estimated, according to EFSA, 2012a.

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 from 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. However, residue levels in nectar and pollen that may occur after such exposure are not available and currently no official guidance is available for these estimations. Therefore, the first-tier risk assessment for bee brood for the situations when bees forage on a crop exposed to dust drift emitted during the drilling procedure cannot be performed. If data on the residues in nectar and pollen would be available, based on this information and on the daily nectar and pollen consumption of bee larvae, the daily uptake of clothianidin could be estimated, according to EFSA, 2012a**.**

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' document, 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 from 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

Dust drift was investigated in 13 field studies (see summaries from **study 10** to **study 22**, in the Study evaluation notes; EFSA 2012d) submitted by the applicant for the authorisation of plant protection products: 7 with treated maize seed, 2 with sugar beet, 2 with winter oilseed rape and 2 with winter barley. Nine studies out of 13 were conducted in Germany, 1 in Austria, 1 in France, 1 in Italy, and in the case of one study the location was not indicated.

Several experiments on dust drift which were conducted in Germany (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, were considered during the Pesticides Peer Review Experts' Meeting 97. Experiments were also performed in Italy within the APENET project (considered in EFSA, 2012c).

The majority of the studies investigated dust drift deposition by measuring the concentrations in Petri dishes as dust traps located at different distances outside of the drilled area. In some studies the aerial or atmospheric dust drift concentration was also measured. In general, on the basis of the available data, it was noted that the deposition decreased with the increase of distance to the sowing area. The aerial or atmospheric dust drift measurements were higher than those from the Petri dishes. In Marzaro *et al.*, 2011 (considered in the APENET project, EFSA 2012c), it is reported that aerial contamination is likely to be the most relevant route of exposure rather than contact with the adjacent vegetation. However, it was noted that in this paper the exposure to ground dust deposition was not investigated. In the experiments performed in Germany it was concluded that the relevant route of exposure is foraging in contaminated areas. Marzaro *et al*., 2011, also concluded that it is important to investigate the mechanism through which honey bees come into contact with the dust to enable effective mitigation measures to be applied. In APENET (EFSA, 2012c), it was also concluded that forager bees are at risk when they fly through the dust clouds emitted by conventional seeders sowing maize seeds coated with clothianidin. In another experiment within the APENET project (Pochi *et al.*, 2012), the application of an innovative air recycling/filtering system resulted in a substantial reduction in the active substance concentration in air.

In the studies submitted by the applicant both mechanical or precision drilling and pneumatic machines were used. The influence of deflectors on the dust deposition was investigated in several studies as well as the influence of film-coating, resulting in a considerable dust drift reduction. Several experiments within the APENET project (Pochi *et al*., 2011, Biocca *et al.*, 2011) showed that the application of air deflectors on pneumatic drilling machines results in a reduction of dust drift deposition. The same findings were observed in the experiments from Germany, where it was concluded that the use of deflectors together with high seed quality were considered to reduce dust emission. However, the experts noted that it was difficult to indicate standard mitigation measures which may cover different Member State situations. Furthermore, acute effects on mortality were observed even with such reduced dust emission, while effects on colony were not observed.

In terms of application rates, it was noted that the studies from the applicant with maize cover all of the authorised uses. The application rates in the studies were from 47 to 133 g a.s./ha (GAP: 25 - 125 g a.s./ha)[13], for other crops the studies were performed with application rates lower than some authorised uses. The application rates in the studies with sugar beet were 60 - 70 g a.s./ha (GAP: 10 - 108 g a.s./ha)[12], with oilseed rape up to 48 g a.s./ha (GAP: 25 - 80 g a.s/ha)[12], and with barley up to 60 g a.s./ha (GAP for cereals: 58.68 - 110 g a.s./ha)[12]. No information was available for other crops. It is also important to note that the dust emission may be influenced by the seed dressing rate, i.e. higher seed dressing rates generated higher dust emission.

For <u>maize</u> the Petri dish deposition ranged from 0.113 to 0.461 g a.s./ha (A. Nikolakis *et al*., 2009 **study 14,** Ch. Neumann, 2005, **study 15,** A. Nikolakis *et al.*, 2008, **study 18;** see Study evaluation notes; EFSA 2012d). The highest aerial measured value was equivalent to 0.80 g a.s./ha (C. Garrido, J. Lückmann, 2010 – interim report, **study 10;** see Study evaluation notes; EFSA 2012d). In two studies, with regard to testing the influence of the film-coating (H.-F. Schnier, 2007 and 2008, **studies**

[13] considering the highest and the lowest 'maximum application rates' authorised in the EU, see Appendix A

16 and **17,** see Study evaluation notes; EFSA 2012d), it was noted that the film-coating can reduce the dust emission and that the dust emission is influenced by the seed dressing rate.

For <u>oilseed rape</u>, in one study the Petri dish 90th percentile value was 0.041 g a.s./ha (A. Nikolakis *et al*., 2008, **study 19;** see Study evaluation notes; EFSA 2012d), while in the other study (J. Lückmann, 2008 **study 20;** see Study evaluation notes; EFSA 2012d), where 1385 samples were analysed, the highest Petri dish value was 0.461 g a.s./ha. This value was detected in 1 sample out of 26 (1.9 %) samples > LOQ; for 1359 (98.1 %) samples clothianidin was < LOQ. This could suggest an overall low dust deposition during the sowing of oilseed rape.

For <u>sugar beet</u> the highest Petri dish value was 0.467 g a.s./ha. (J Lückmann, T. Städtler, 2009 **study 11;** see Study evaluation notes; EFSA 2012d). Clothianidin was detected > LOQ in 3 samples out of 1390 (0.2 %), for 1387 (99.8 %) samples clothianidin was <LOQ. In the other study (A. Nikolakis *et al*., 2008, **study 12,** see Study evaluation notes; EFSA 2012d) clothianidin was quantified in 1.5 % of samples considering the ground deposition, while it was detected above the LOQ in 75 % of the samples considering the atmospheric drift: residues were detected above the LOQ up to 5 m height and 30 m distance from the “zero-line”.

For <u>barley</u> (A. Nikolakis *et al*., 2008, **study 21,** see Study evaluation notes; EFSA 2012d), the highest Petri dish 90th percentile value, considering the ground deposition, was 0.033 g a.s./ha (pneumatic machine) and 0.029 g a.s./ha (mechanical machine), while considering the aerial dislocation of ground dust deposition, clothianidin was quantified only in 2 out of 180 samples. However, considering the atmospheric dust drift, the highest 90th percentile value was 0.212 g a.s./ha (pneumatic machine): residues were detected above the LOQ up to 5 m height and 30 m distance from the “zero-line”.

According to EFSA 2012a, the deposition of dust (highest detected level) to the off-crop area can be compared with the acute toxicological endpoints from the laboratory studies in order to derive HQ values. When the Petri dish concentration is available, a factor of 10 should be applied as suggested by EFSA 2012a. A trigger of 50 is still suggested in EFSA 2012a. However, the available deposition data set was questioned during the peer review. In particular, the seeds used in the field trials were considered to be of high quality, and hence not representative of standard EU situations. Therefore this assessment was not performed and instead the HQ values based on the values from the draft ‘Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012’ document were considered (Table 3).

In 3 out of 13 studies effects on honey bees were investigated by placing colonies in the study fields. In particular, 2 semi-field studies, where small hives were exposed to abraded dust concentration from maize seeds and barley seeds were available, and a field study was available where the bee assessment included observation of effects on mortality, colony development and food store.

In the semi-field studies (Neumann P., Bakker F., 2010, **study 13,** Nikolakis A. *et al*., 2011, **study 22;** see Study evaluation notes; EFSA 2012d) NOERs of below 0.5 and 0.1 g a.s./ha for mortality are derived, respectively.

In both studies, no effects on the number of eggs, larvae and sealed brood were observed as treatment related. In the study with abraded dust from barley, the NOER value for colony, considering all parameters (i.e. strength of the colony, presence of healthy queen, comb area with pollen and nectar, and comb area containing eggs, larvae, and capped cells), was 2 g a.s./ha, which might indicate that the risk for the colony following the exposure to dust deposition is low, based on the available deposition measurements for barley as reported above. This NOER is less than the predicted off-field exposure for the authorised uses in cereals and therefore could be considered to indicate a low risk. However, several limitations were identified in EFSA 2012a as regards the extrapolation of the results from semi-field tests to colony level. Both studies were further considered during the Pesticides Peer Review Experts’ Meeting 97. Due to some deficiencies in the presentation of the results, the experts concluded that it is not possible to use the endpoints from the study with barley abraded dust in a regulatory risk assessment. The experts agreed that a re-evaluation of the raw data as regards the effect on brood would be necessary. The study with abraded maize was also considered as not useful for risk assessment, since the study design did not allow the derivation of an endpoint from dust exposure (NOER below 0.5 g/ha).

A regards the field study (C. Garrido, J. Lückmann, 2010 – interim report, **study 10**; see Study evaluation notes; EFSA 2012d) conducted in Austria (formulation product Poncho Pro, maize crop, with a calculated application rate of 132 g a.s./ha and a dressing rate of 1.250 mg a.s./seed), it was observed that the mean mortality in the treatment group was above that of the control group. No statistical analysis was available therefore it was not possible to conclude on the significance or biological relevance of this difference. In the same study the colonies were assessed before the hibernation and were considered to have sufficient strength to hibernate (only one colony in the treatment group showed symptoms of Chronic Bee Paralysis Virus). As regards the sublethal effects, bee colonies were observed to be very aggressive during the sowing, but this effect was transient. This study was further considered at the Pesticides Peer Review Experts' Meeting 97. The experts noted that the exposure was not uniform for all the colonies. A re-analysis of the results by separating the colonies exposed to worst case conditions from upwind colonies, where exposure is expected to be limited, would be necessary.

2.1.5. Conclusion on the risk via dust drift

Overall, on the basis of the available data, it could be concluded that maize seeds produce the highest dust drift deposition, while for sugar beet, oilseed rape and barley seeds the dust drift deposition was very limited. No information was available for other crop seed, i.e. alfalfa, cereals other than barley, chicory, clover, mustard, sunflower and poppy. Since one of the factors influencing the abrasion is the crop (seed), extrapolation of data to other crops is highly uncertain. Extrapolation would likely be possible for similar cereals (e.g. wheat, oat, rye), but less reliable to all other crops.

As regards the first-tier risk assessment based on the HQ values calculated with deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012', a high acute risk was not excluded for bees foraging or flying in adjacent crops during the sowing of maize, oilseed rape, and cereals. It has to be noted however, that this conservative assessment is 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. For information, it should be noted that the deposition values used to calculate the HQ values were considered within the draft EFSA guidance document for bees[14] and 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. The first-tier risk assessment could be considered low for sugar beet (assuming a trigger of 50).

For the authorised uses on **maize** the available higher tier data overall exclude a high long-term risk to the colony, but some uncertainties were also indicated and the bee mortality was higher than the control. Therefore, it was concluded to identify a data gap to further address the risk (i.e. the acute

[14] 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).

and the long-term risk to colony survival and development, and the risk to bee brood) following dust exposure.

For the authorised uses on **oilseed rape**, **barley** and **sugar beet** no field effects data were available but the low dust residue deposition observed in higher tier studies might suggest a low exposure and hence a low risk (i.e. the acute and long-term risk on colony survival, development, and the risk for bee brood). However, the studies available were performed in Germany with specific plant protection products and with application rates lower than some authorised uses. Furthermore, the experts at the meeting noted that the seed dressing quality used in the exposure studies may not be representative of the seed dressing quality for the authorised products in the EU. Information was not available to determine whether the conditions in the studies were typical for Germany or whether extrapolation may be possible to other plant protection products authorised in the EU. Therefore, for the uses on **oilseed rape** and **barley** it was not possible to draw a firm conclusion. Without information to support the representativeness of the exposure estimates a quantified risk assessment could not be performed. A data gap is identified to further address the potential dust 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). For the uses on **sugar beet** and **fodder beet/beet** (assuming the same technology for seed pelleting and drilling), the low risk to honey bees, which was concluded on the basis of a tier 1 risk assessment, was also confirmed by some higher tier field studies investigating dust deposition, which indicated low and infrequent dust deposition.

Since no data were available for the authorised uses on **alfalfa, cereals other than barley, chicory, clover, mustard, sunflower and poppy**, a data gap is identified to further address the potential dust 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 GAP tables did not specify whether any crops would be sown 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 is important to highlight that mitigation measures such as application of deflectors, air recycling systems, and high seed quality were considered useful to reduce the dust exposure, but it was difficult to identify standard mitigation measures which may cover different Member State situations.

It should 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 (survival and behaviour). No information on residues in nectar in the adjacent vegetation following dust drift were available.

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

A key element for the risk via residues in pollen and nectar is the attractiveness of the crop, including whether agronomic practices will allow the crop to flower. Some of the crops on which clothianidin 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. The crops on which clothianidin is authorised are grouped based on their attractiveness to honey bees as follows:

- <u>Attractive crops</u> to honey bees for nectar and/or pollen**: alfalfa** (minor use), **clover** (minor use) **maize** (corn), **mustard, oilseed rape, sunflower, poppy**

- <u>Non-attractive crops</u> to honey bees for nectar and/or pollen**: chicory, fodder beet, sugar beet, beets, cereals (wheat, barley, oat, rye, triticale)**.

This allocation is based on the list compiled in the Netherlands for the same purposes (Ctgb, 2011). The list focuses on attractiveness of nectar or pollen and does not take into account other matrices that may attract bees such as guttation fluids or honey dew. Potentially honey bees could forage on insect honey dew present in the treated crops. It may be argued that insect honey dew will not be present in crops grown from clothianidin treated seed as the purpose of the seed treatment is to prevent crop pests, including aphids. However, no information was available to demonstrate that the seed treatment will prevent the formation of insect honey dew. Therefore, with the information available, it cannot be excluded that there is a potential risk to bees from foraging on insect honey dew. A data gap is therefore concluded.

It should be noted that the attractiveness of a crop to honey bees is not necessarily the same for other pollinators.

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[15] and for the current mandate for neonicotinoids. Regarding clothianidin, information from 30 outdoor studies on 3 crops, i.e. oilseed rape (13 out of 30), sunflower (2 out of 30) and maize (15 out of 30) were available in this database (see Appendix B). For the risk assessment, these residue values were expressed as RUD (residue unit dose) to make them independent from the application rate used in the studies. RUD calculations were performed only for the studies where residues were detected > LOD and detailed information on the application rate was available. These values are summarised in Table 4, below. It was noted that in several residue studies (11 out of 30) clothianidin was measured < LOQ of 0.001 mg/kg. The majority of the residues below the LOQ were detected in oilseed rape (8 studies out of 11), while maize pollen residue was detected below the LOQ in 2 studies.

[15] 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.

Table 4: RUD values of clothianidin for pollen and nectar referring to application rate of 1 kg/ha or 1 mg/seed

	RUD (Nectar)	RUD (Pollen)
oilseed rape	0.024-**0.2** mg/kg based on application rate of 1 kg/ha	0.011-**0.238** mg/kg based on application rate of 1 kg/ha
sunflower	**0.012** (Residues in nectar were not detected due to insufficient sample. As a surrogate, the LOD of **0.0003** mg/kg was used to derive a RUD).	0.114-**0.122** mg/kg based on application rate of 1 kg/ha
maize	Not applicable	0.027-**0.295** mg/kg based on application rate of 1 kg/ha (0.003-0.028 mg/kg based on seed dressing rate of 1 mg/seed);

Values in bold were used to estimate the residue intakes. **Note:** whether a RUD value refers to 1 kg/ha or 1 mg/seed depends on the information that was available in the respective studies.

The level of residues that are expected to be 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, i.e. oilseed rape, sunflower and maize. Moreover, in order to achieve a worst case risk assessment it should be demonstrated that the conditions of the study 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 also important to note that the RUD values in Table 4, above, have been derived from studies conducted mainly in Germany. There are uncertainties with the extrapolation of this residue information to other situations in the EU, for example, due to climatic and environmental influences.

2.2.1. First-tier acute risk assessment

EFSA, 2012a suggests to calculate an ETR_{acute} (acute exposure to toxicity ratio) 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, based on the residues in nectar and pollen and the daily nectar and pollen consumption of bees, the daily uptake of clothianidin can be estimated. The available residue information (in the form of RUD values) was presented in Table 4, above.

Regarding the feed consumption, EFSA, 2012a reported data for different castes of bees. Forager bees consume only nectar while for nurse bees a mixed pollen and nectar diet was considered. 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:

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

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

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)

<u>Oilseed rape</u>

Based on the data submitted by the Member States, clothianidin is authorised as a seed-dressing under several product names (see Appendix A). The application rates are between 25 and 80 g a.s./ha[16]. Considering these doses and the highest available RUD values from Table 4, the calculated residue levels (expressed in µg/kg) were:

- residue level in nectar between 5 and 16 µg/kg;
- residue level in pollen between 5.95 and 19.04 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 (Cn) was estimated to be:

- nectar consumption (Cn): 213 - 853 mg/bee/day for a forager;
- nectar consumption (Cn): 227 - 333 mg/bee/day for a nurse bee.

As regards the pollen consumption (Cp), the highest value was taken into account, i.e. 12 mg pollen/nurse bee/day.

Using the calculated residues levels and the higher value for consumption (Cn and Cp), the residue intake (RI) for the lowest and the highest 'maximum application rate' respectively, (expressed in ng/bee/day) was:

- $RI_{forager}$: 4.27 – 13.65 ng/bee/day for a forager;
- RI_{nurse}: 1.74 – 5.56 ng/bee/day for a nurse bee.

[16] considering the lowest and highest 'maximum application rates', see Appendix A

Sunflower

Based on the data submitted by the Member States, clothianidin is authorised as a seed-dressing on sunflower in 2 EU Member States (see Appendix A). The application rate is 27 g a.s./ha. Considering this dose and the highest available RUD values from Table 4, the estimated residue levels were reported below (expressed in µg/kg). As mentioned in Table 4, the RUD value was calculated for nectar based on the LOD.

- residue level in nectar: 0.324 µg/kg (i.e. based on LOD);
- residue level in pollen: 3.29 µg/kg.

Assuming 15 % as a realistic worst case estimation for sugar content of sunflower nectar to be relevant for risk assessment, the nectar consumption was estimated to be:

- 213 - 853 mg/bee/day for a forager;
- 227 - 333 mg/bee/day for a nurse bee.

As regards the pollen consumption (Cp), the highest value was taken into account, i.e. 12 mg pollen/nurse bee/day.

Using the calculated residues levels and the higher value for consumption (Cn and Cp), the residue intake (RI) was calculated to be (expressed in ng/bee/day):

- $RI_{forager}$: 0.28 ng/bee/day for a forager
- RI_{nurse}: 0.15 ng/bee/day for a nurse bee.

Maize

Based on the data submitted by the Member States, clothianidin is authorised as a seed-dressing under different product names (see Appendix A). The application rates are between 25 and 125 g a.s./ha[17].

Considering these doses and the highest available RUD value from Table 4, the calculated residue levels in pollen (expressed in µg/kg) were between 7.38 and 36.88 µg/kg. Using the calculated residues and the highest of the pollen consumption data, i.e. 12 mg pollen/nurse bee/day, the residue intake (RI) for the lowest and the highest 'maximum application rate', was calculated to be (expressed in ng/bee/day):

- RI_{nurse}: 0.089 – 0.443 ng/bee/day for a nurse bee.

Considering the above ingestion rates from oilseed rape, sunflower and maize, the ETR_{acute} values were calculated on the basis of the oral LD_{50} of 0.00379 µg a.s./bee and reported in Table 5, below.

[17] considering the lowest and highest 'maximum application rates', see Appendix A

Table 5: Calculation of ETR_{acute} values for the authorised uses on oilseed rape, sunflower and maize

Crop	Application rate	Forager bee			Nurse bee		
		RI (ng/bee/d)	LD_{50} (ng/bee)	ETR	RI (ng/bee/d)	LD_{50} (ng/bee)	ETR
Oilseed rape	lowest 'maximum application rate' = 25 g/ha	4.27	3.79	1.13	1.74	3.79	0.46
	highest 'maximum application rate' = 80 g/ha	13.65	3.79	3.6	5.56	3.79	1.47
Sunflower	application rate = 27 g/ha	0.28	3.79	0.07	0.15	3.79	0.04
Maize	lowest 'maximum application rate' = 25 g/ha	-	3.79	-	0.089	3.79	0.02
	highest 'maximum application rate' = 125 g/ha	-	3.79	-	0.443	3.79	0.12

The first-tier ETR_{acute} values greater than 1 clearly indicate a high risk for forager and nurse bees following the ingestion of contaminated nectar and pollen. Concerning the ETR_{acute} values below 1, there are no agreed trigger values for the interpretation of the risk assessment and therefore it is not possible to conclude. Moreover, there are a number of uncertainties with the data used to derive the exposure estimates. The RUD values in Table 4, above, have been derived from studies conducted mainly in Germany, and the relevance and severity of the conditions of the studies to other situations in the EU is not known.

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 expressed as daily uptake. A 10-day chronic study was available in the dossier submitted by the applicant. The NOEC in this study was 10 µg a.s./L, and the LC_{50} >10 µg a.s./L. This endpoint can be expressed as 0.00813 mg/kg diet, assuming a sugar density of 1.23 kg/L (EFSA, 2012b).

Since the available endpoint (NOEC) is expressed in terms of a concentration in the food (mg/kg) rather than a daily uptake value (µg/bee/day), these assessments cannot be performed. However, to make the best-use of the available data for clothianidin, an illustrative assessment can be performed by direct comparison of the concentration in relevant matrices (pollen and nectar) to the available NOEC in terms of µg/kg. It must be noted that this surrogate assessment does not account for the 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 such a surrogate assessment, performed using concentrations, because it might be less conservative than if actual intake of the bees was accounted for.

Since forager bees consume only nectar, the residue concentrations in nectar, estimated based on the application rates and the RUD values in Table 4, can directly be compared with the toxicity endpoint.

Since for a nurse bee a mixed nectar and pollen diet was reported in EFSA 2012a, the overall residue concentrations (in the mix of pollen and nectar) need to be calculated and these concentrations can be compared with the toxicity endpoint. The combined concentration can be calculated by using the following formula:

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

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 worst case, the lowest nectar consumption and the highest pollen consumption were taken into account in order to consider the higher residue level observed in pollen rather than in nectar. The lowest estimated range of nectar consumption was calculated to correspond to a nectar sugar content of 65 % and was 52.3 - 76.9 mg nectar/bee/day. The minimum nectar consumption of 52.3 mg nectar/bee/day was used in the calculations. The highest pollen consumption considered was 12 mg pollen/day.

The residue concentrations (mix of pollen and nectar) was calculated for oilseed rape, sunflower and maize, based on the application rates, and the RUD values, or considering residues equal to zero for maize nectar (since maize does not produce nectar), reported in Table 4. The nectar and pollen concentrations for oilseed rape, sunflower and maize can directly be compared with the toxicity endpoint. The comparison is reported in Table 6, below.

Table 6: Comparison of the endpoint for the chronic risk assessment for forager and nurse bees with the residue levels in nectar and with the calculated residue concentrations (residue levels for foragers and RC for nurse bee) in the mixed diet of nurse bees

	Forager bee			**Nurse bee**		
	oilseed rape	sunflower	maize	oilseed rape	sunflower	maize
Residue level/RC for the lowest ‘maximum application rate’	0.005 mg/kg	0.000324 mg/kg	-	0.001577 mg/kg	0.00088 mg/kg	0.00138 mg/kg
Residue level/RC for the highest ‘maximum application rate’	0.016 mg/kg		-	0.016567 mg/kg		0.00688 mg/kg
Chronic endpoint (NOEC)	**0.00813 mg/kg**					
Ratio (NOEC/residue levels or RC) for the lowest ‘maximum application rate’	1.63	25.09	-	5.6	9.26	5.89
Ratio (NOEC/residue levels or RC) for the highest ‘maximum application rate’	0.51		-	0.49		1.18

The estimated concentrations in bee relevant matrices are in some cases lower than the chronic NOEC of 0.00813 mg/kg. This could be interpreted to indicate a low chronic risk to forager honey bees for oilseed rape (lowest ‘maximum application rate’) and sunflower, if safety factors of 1.63 and 25.09, respectively, were considered to be sufficient; or a low risk chronic risk to nurse bees for oilseed rape (lowest application rate), sunflower and maize, if a safety factor of 5.6, or 9.26 or 1.18 respectively, were considered to be 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.

2.2.3. First-tier risk assessment for brood

EFSA, 2012a suggests to calculate 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) for larvae. Since the available toxicological endpoint for larvae was not expressed as daily uptake, the same approach described in section 2.2.2 was applied.

Based on the EFSA, 2012a, for a bee larva a mixed nectar and pollen diet was considered. The sugar consumption for larvae was 59.4 mg sugar/larva, which in terms of nectar consumption corresponds to 91.4 mg nectar/larva, while the pollen consumption was 2 mg pollen/larva.

The nectar and pollen residue concentration for oilseed rape was 0.00501 mg/kg for the lowest ‘maximum application rate’ and 0.016 mg/kg for the highest application rate; for sunflower it was 0.000388 mg/kg, for maize it was 0.00026 mg/kg for the lowest ‘maximum application rate’ and 0.00079 mg/kg for the highest application rate.

The estimated residue levels (RC) were directly compared with the toxicity endpoint, i.e. the $NOEC_{larvae}$ of 20 µg a.s./kg.

Table 7: Comparison of the toxicity endpoint with the calculated residue levels in pollen and nectar for brood (RC)

	Larvae		
	oilseed rape	sunflower	maize
Residue level (RC)for the lowest ‘maximum application rate’	0.00501 mg/kg	0.000388 mg/kg	0.00026 mg/kg
Residue level (RC) for the highest ‘maximum application rate’	0.016 mg/kg		0.00079 mg/kg
Chronic endpoint (NOEC)	**0.02 mg/kg**		
Ratio (NOEC/RC) for the lowest ‘maximum application rate’	39.9	51.60	76.92
Ratio (NOEC/RC) for the highest ‘maximum application rate’	12.5		25.32

The estimated concentrations in bee relevant matrices are lower than the chronic NOEC of 0.02 mg/kg. This could be interpreted to indicate a low risk to brood for oilseed rape, sunflower and maize, if a safety factor of 12.5, 51.6 and 25.32, 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.

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 (survival and behaviour). Nevertheless, using the available information for clothianidin and the same approach as for the acute risk assessment, a first-tier sublethal risk assessment was performed. The ratios were calculated between the residue intakes (RI), reported in section 2.2.1, and the sublethal dose of 0.5 ng/bee, where behavioural effects where observed (as tested in the paper by Schneider *et al.* 2012 and considered in EFSA, 2012b). These calculations (Table 8) were only performed for foragers because the dose tested by Schneider *et al.* 2012, was administered as sucrose solution to foragers, which is comparable with the consumption of nectar (main route of exposure for foragers, EFSA 2012a).

Table 8: First-tier sublethal risk assessment on the basis of the ratio between the ingestion rates reported in section 2.2.1 and the sublethal dose of **0.5 ng/bee** (Schneider *et al.* 2012) for the authorised uses on oilseed rape and sunflower

Crop	Application rate g a.s./ha	Ingestion rates (ng/bee/d)	Sublethal dose (ng/bee)	Ratio (forager bee)
Oilseed rape	lowest 'maximum application rate' = 25 g/ha highest 'maximum application rate' = 80 g/ha	4.27 13.65	0.5	8.53 27.31
Sunflower	application rate = 27 g/ha	0.28	0.5	0.56

For the authorised uses in oilseed rape the calculated exposure exceeds the sublethal dose of 0.5 ng/bee. For sunflower the calculated exposure is less than the sublethal dose. Currently there are no agreed trigger values (or a risk assessment scheme) for sublethal effects. A low risk to honey bees from exposure to sublethal doses cannot be concluded on the basis of the above risk assessment.

2.2.5. Risk assessment using higher tier studies

Several semi-field studies (cage and tunnel test) and field studies were reported in the DAR and were reconsidered in the present conclusion in view of EFSA, 2012a. Further higher tier studies were also available in the dossiers submitted for the authorisation of plant protection products.

2.2.5.1. Studies from the DAR

Three cage studies were performed on the effects of clothianidin on foraging honey bees in summer rape, in different countries (Sweden, UK, France) (Belgium, 2003). The residues were analysed and the results were included in the residue data set in Appendix B. The trial was conducted using tents with a surface area of 16 m², with a small colony of 5000 bees and a study duration of 3 - 4 days. It was concluded in the DAR that no mortalities or abnormal behaviour effects were observed. However, taking into consideration the distance between the hive and the crop, which is a key factor in order to ensure that nectar foragers are exposed through ingestion, it was noted that foraging (some meters) in a small cage (16 m²) means less energy consumption and low consumption of collected nectar, and therefore lower exposure through ingestion of nectar for flight energy than during real and longer-distance foraging flights. Moreover, as the colonies have food reserves, during their brief period in the cages (3 – 4 days) honey bees can simply not consume (or consume only small amounts) nectar or pollen gathered on the experimental crops, and instead they can feed using the food stocks previously stored in the colony. Therefore, honey bees may not ingest the pollen and nectar coming from the treated plots or ingest only a small amount during the observation period.

A number of studies have been conducted in tunnels of 50 m²:

- Two studies for testing the effects of residues on foraging honey bees in <u>summer rape</u> (dressed seeds) (Maus Ch. & Schöning R., 2001b and 2001c; Belgium, 2003).
- Two studies for testing the effects of residues on foraging honey bees in <u>sunflowers</u> (dressed seeds) (Maus Ch. & Schöning R., 2001d and 2001e; Belgium, 2003).

- One study for testing the development, the behaviour and the mortality of honey bees in a very small colony (500 bees) exposed to contaminated pollen for 40 days (Maus Ch. & Schöning R., 2001h; Belgium, 2003).

- One study for testing the development, the behaviour and the mortality of honey bees in a very small colony (500 bees) exposed to contaminated honey for 43 days (Maus Ch. & Schöning R., 2001i; Belgium, 2003).

- One study for evaluation of the effects of residues of clothianidin in maize pollen from dressed seeds (Maus Ch., 2002d; Belgium, 2003).

In several of the above study summaries it is mentioned that no raw data on mortality or behaviour were included, therefore it was not possible to validate the results and it was concluded that these were not appropriate for the current risk assessment. In some cases, the mortality was higher in the control than in the treatment group, sometimes it was the contrary. However, no statistical analysis was available to investigate the significance of these differences. The studies with small colonies (500 individuals) appear unrealistic with respect to the normal conditions of a bee colony of several thousands of individuals. For the study from Maus Ch., 2002d, the residue concentration in the pollen used (0.8 µg/kg with the seed dressed with 1 g a.s./100 seeds, equivalent to a RUD of 0.008 mg/kg) is largely below the levels found in other experiments and considered in the residue data set (in Table 4 the highest RUD for maize is 0.028 mg/kg based on a seed dressing rate of 1 mg/seed). Therefore, the results of this experiment could not be considered as representative worst case exposure to maize pollen.

Two field tests were available: one performed in Germany and the other in Canada. The study conducted in Germany (Maus Ch. & Schöning R., 2001a; Belgium, 2003) aimed at investigating mortality in front of the hives, colony weight gain, syrup consumption, and the average number of foragers at the feeder and arriving to the hive. It was conducted with a small colony (5000 to 10 000 bees), containing food combs. The feeder was placed at a distance of 165 m from the hive. Concerning mortality, the results were not considered as valid since wasps were observed to remove dead bees from the sheets in front of the hives. Concerning behaviour, it is mentioned that no abnormal behaviour was observed. However, the short distance from the colonies to the feeder does not allow to confirm that foragers consumed the contaminated nectar they foraged. The distance between the control and the treated plots was not specified and therefore it is not possible to verify whether cross-foraging between the control and experimental colonies was avoided. Concerning the observations on the behaviour of the bees, it is not specified which behaviour elements have been carefully observed. The study in Canada (Scott-Dupree C.D. & Dr. Spivak M.S., 2001; Belgium, 2003) cannot be considered useful for the risk assessment. No untreated control field was present and the treated field was treated with a mixture of three molecules.

2.2.5.2. Studies from dossiers submitted for the authorisation of plant protection products

Laboratory studies

Two *ad hoc* laboratory studies were available to investigate the carry-over of clothianidin from spiked bee bread to honey royal jelly and to investigate the effect of clothianidin on honey bee food gland development (Simoens and Jacobs 2005a, **study 35,** Simoens and Jacobs 2005b, **study 36** see Study evaluation notes; EFSA 2012d). The results of the first study indicated that clothianidin is not transferred to the royal jelly and therefore to a generation of bees not directly exposed to the crop (nominal exposure: 9 µg/kg, residue detected < LOD = 0.3 µg/kg). The second study indicated that an exclusive nurse bee diet with pollen and honey (pollen 50 %, honey 50 %) at a nominal concentration of 9 µg/kg did not affect the development of the food gland (i.e. hypopharyngeal glands). Whilst the study designs are scientifically interesting and original, the study sensitivity is unknown, and therefore their use in a regulatory risk assessment is limited without further developments or research.

<u>Field studies</u>

Several long-term field studies were available for maize while only one study was available for oilseed rape.

- Three multi-year studies were conducted in different sites in France in maize fields with the product Clothianidin FS 600 B G (Hecht-Rost S. 2009, **studies 25, 26** and **27;** see Study evaluation notes; EFSA 2012d);

- One study was performed in Canada in oilseed rape (canola) field (Cutler C., 2009 **study 23;** see Study evaluation notes; EFSA 2012d**)**.

- One study from Germany was also available where bee colonies were monitored following damage caused by sowing of maize seed treated with 'PonchoPro' in spring 2008 (Liebig G., 2008 **study 30;** see Study evaluation notes; EFSA 2012d**)**. In addition, two studies were available where the relationship between the use of 'PonchoPro' treated maize seeds, and their seed treatment quality to the reported bee damage was statistically investigated (Schad T. *et al*., 2008, studies **28** and **29;** see Study evaluation notes; EFSA 2012d).

As regards the studies in France (Hecht-Rost S. 2009, **studies 25, 26, 27)**, the parameters considered were mortality, foraging activity, behaviour, brood development and strength of the colony. It was noted that the exposure in these studies did not represent a worst case with respect to other residue data in maize (the highest RUD value from these studies was 0.012 mg/kg based on a seed dressing rate of 1 mg/seed, compared to the RUD of 0.028 mg/kg based on a seed dressing rate of 1 mg/seed, as reported in Table 4). Moreover, in these studies some weak points were noted, such as field size, distance between fields, and presence of attractive crops close to the study area. In one study (**study 25**, conducted in Languedoc – Roussillon; see Study evaluation notes; EFSA 2012d) adverse effects on the colony could not be excluded, i.e. the average colony strength showed weaker development in the hives from the treated field, although they could overwinter. Due to the study design (hives were placed adjacent to the treated crop), the studies cannot be considered to cover all potential adverse effects which could occur following sublethal exposure, e.g. homing failure of forager honey bees.

The study performed in Canada (Cutler C., 2009, **study 23**) was not considered reliable for the risk assessment due to several deficiencies identified, i.e. colony size was not reported, plot size and distance between the treated and control plots was too small (250 m), behaviour effects were not investigated, and residue was detected in some control samples.

In the monitoring study in Germany (Liebig G., 2008, **study 30**) the development of twelve productive colonies from two apiaries severely affected by high mortality in spring following dust drift was monitored between May and October by means of regular population surveys at 21-day intervals. Six new colonies were placed in the contaminated pollen combs and six new colonies were used as control. Both new colonies developed in the normal way in the observation period from June to October. There were no brood losses and no excessive bee mortality. A dilution effect due to the continued collection of pollen probably had a part to play. It is also likely that there was a dilution effect on the productive colonies, which were damaged at the end of April, as they had already recovered by early summer. No further developmental disorders occurred during the maize flowering season. In addition, the development of the twelve new colonies was monitored at each site until the colonies were put into overwintering in October. No particularly striking differences occurred before the bees were placed into overwintering. The small breeding colonies, formed at a later stage than the other colonies, developed extremely well, indicating that the conditions for bee colonies in the Rhine valley in late summer and autumn were not unfavourable. Based on the statistical analysis in Schad T. *et al*., 2008 (**studies 28** and **29)**, it was indicated that 'PonchoPro' seed treatment can be used without causing exposure of bees, by using seeds of good quality and low dust emission sowing machinery. The German studies were considered useful as additional information.

Field studies were also further considered at the Pesticides Peer Review Experts' Meeting 97. In general, the experts considered that field studies are difficult to interpret, and in particular to differentiate between the large natural variation in bee field studies and the effect of a treatment. The experts noted that it is difficult to conduct worst case studies in maize because it is not a highly attractive crop to honey bees. It may be necessary to include additional sugar to attract the bees. Based on monitoring information in Austria, the highest percentage of maize pollen found in bee bread was 8.1 %, which is considered to be low. Similar investigations in Germany indicate that pollen can be foraged under worst case conditions but even in these studies the bees managed to find other sources of pollen. Overall, the experts concluded that the conditions of the studies were currently not worst case. However, further research / collection of available literature regarding the use of maize pollen by honey bees might be useful to support the severity of the studies in relation to pollen collection.

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

First-tier acute, chronic and brood risk assessments were carried out for **oilseed rape**, **sunflower** and **maize** seed treated with clothianidin. Exposure (either residue intakes or residue concentrations) exceeded the toxicity endpoints for oilseed rape (for the acute risk and for the chronic risk at the highest application rate) and it was below the toxicity endpoints for maize and sunflower. Where the exposure exceeded the toxicity endpoints a high risk was clearly indicated. However, no agreed trigger values are available for the interpretation of results where exposure is below the toxicity endpoints, therefore, in such cases (i.e. maize and sunflower) it is not possible to conclude a low risk. For **other uses** as seed treatments reported in the GAP table (Appendix A), i.e. alfalfa, clover, mustard and poppy, a quantitative first-tier risk assessment was not carried out since no specific residue data were available and extrapolation from other crops was considered uncertain. However, a low risk might be concluded for the uses authorised in a number of crops, which are unlikely to be foraged for pollen or nectar by bees, i.e. **chicory, fodder beet, sugar beet, beets, cereals (wheat, barley, oat, rye, triticale).**

As regards the first-tier sublethal risk assessment, the comparison with the sublethal dose of 0.5 ng/bee (Schneider *et al.*, 2012) showed that residue intakes for oilseed rape were notably higher than the sublethal dose (as also reported in the EFSA 2012b), but lower for sunflower. Since no trigger values are available a low risk cannot be concluded for sunflower and oilseed rape. However, it is highlighted that currently there is no agreed testing strategy for the assessment of sublethal effects. It is also not fully understood what type of sublethal effect could potentially lead to adverse effects on honey bee survival and behaviour.

It is highlighted that the residue intake estimations (i.e. the consumption value and the sugar content percentage) represent worst case scenarios. Further higher tier refinements might be performed. For example, data on metabolism in bees, dilution factors, or specific sugar content in the crops could be considered in these calculations, but no agreed approaches are currently available. It should also be noted that the highest residue levels were used for the intake estimation. The experts at Pesticides Peer Review Experts' Meeting 97 expressed a concern over the comparison of the very worst case residue found in all studies performed (in the EU). The experts considered that such a comparison would be better performed for individual Member States, taking into account the authorised GAP in the Member State and accounting for environmental and climatic conditions. Whilst this approach is agreed in principle, it is noted that limited data are available and the requested risk assessment is for all of the authorised uses in the EU. A larger residue data set might be useful for a better definition and representativeness of the residue levels.

As regards the higher tier studies available in the DAR, they could not be considered appropriate for risk assessment following the exposure to residues transferred to pollen and nectar of plants grown from treated seed.

As regards the field studies in the dossiers submitted for the authorisation of plant protection products, several uncertainties were noted in the studies performed in maize (France) to investigate long-term effects on the colonies, including some potential sublethal effects. However, the experts at Pesticides Peer Review Experts' Meeting 97 noted that it is difficult to conduct worst case studies in maize because it is not a highly attractive crop for honey bees. Further research/collection of available literature regarding the use of maize pollen by honey bees might be useful to support the severity of the studies in relation to pollen collection.

Overall, the following conclusions were drawn:

For the authorised uses on **maize**, on the basis of the available data it was concluded that the acute risk and the long-term risk to colony survival and development, including the risk to bee brood, and the risk from exposure to sublethal doses following the ingestion of contaminated nectar and pollen need to be further considered, and a data gap has been identified.

For the authorised uses on **oilseed rape**, the acute risk, and the chronic risk (at the highest application rate) was indicated as high by the first-tier risk assessment. No valid higher tier studies were available, therefore a data gap was identified to further consider 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 **other** authorised **uses** in **attractive crops** to honey bees (for nectar and/or pollen), i.e. **alfalfa, clover, mustard, sunflower** and **poppy**, no data (either residue data or higher tier studies) were available. Therefore, it is not possible to finalise the risk assessment following the ingestion of contaminated nectar and pollen, 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, and a data gap is concluded.

A low risk can be concluded for the uses authorised in a number of crops, which are unlikely to be foraged for pollen or nectar by bees, i.e. **chicory, fodder beet, sugar beet, beets, cereals (wheat, barley, oat, rye, triticale)**.

2.3. Risk via systemic translocation in plants – guttation

2.3.1. First-tier risk assessment

Currently there is no agreed approach for a first-tier risk assessment for bees from exposure via residues in guttation fluid. EFSA 2012a indicates that ETR_{acute}, $ETR_{chronic}$ and ETR_{larvae} should be calculated for potential exposure via guttation fluid. However, insufficient information is available regarding the water consumption of forager bees, in-nest bees and bee brood, and therefore it is not possible to calculate first-tier ETR values. As a form of screening step, to understand the potential risk to bees, a comparison can be made between the acute toxicity of clothianidin and the concentrations found in the guttation fluid. 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 clothianidin to honey bees is 0.00379 μg a.s./bee. The highest residue of clothianidin in guttation fluid was 717 mg/L, measured in a selected sample from the 1st week after emergence (Luckman, 2010, **study 1;** analytical part, see Study evaluation notes; EFSA 2012d). It can be estimated that a honey bee would have to consume 0.005 µL of guttation fluid to reach the acute oral LD_{50}.

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

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

2.3.2. Risk assessment using higher tier studies

A number of higher tier field studies investigating the phenomenon of guttation were available, as well as a position paper based on a glasshouse experiment on maize. Seven studies out of 9 investigated guttation in maize, 1 in sugar beet and 1 in winter oilseed rape. The aim of these studies was, generally, to monitor guttation occurrence, bee activity, mortality, relevance of guttation as a water source, and potential effects on the colony (colony strength and brood development). The field studies were performed in France (4), Austria (1), Switzerland (2) and Germany (1). The studies were in general well designed and could be considered appropriate to investigate potential exposure to guttating plants.

Chemical analysis of guttation was performed in 3 out of the 9 studies (2 studies in maize and 1 in oilseed rape). High residues of clothianidin were measured in the guttation fluid from maize plants grown from treated seed: up to 717 mg a.s./L in the study performed in Austria (Luckman, 2010, **study 1;** see Study evaluation notes; EFSA 2012d**)**, and up to 37 mg a.s./L in the study performed in Switzerland (Federal Department of Economic Affairs, 2009, **study 7;** see Study evaluation notes; EFSA 2012d). High values were also detected by Tapparo *et al.*, 2011 (up to 102 mg a.s./L) in maize plants sown in greenhouse. The residue levels were observed to decrease considerably after emergence during the observation period, although Tapparo *et al.*, 2011 reported an increasing trend during the last 10 days after emergence. In the study where residue analysis in oilseed rape was performed (study performed in Germany by Hofmann *et al.*, 2010, **study 9bis;** see Study evaluation notes; EFSA 2012d), the residue level was 0.41 mg a.s./L. In the analytical part of **study 1** and **study 9bis**, residue analysis in dead bees was also performed and residue levels up to 384.9 µg/kg and 2.9 µg/kg were detected, respectively.

In all of the studies conducted using treated maize seeds, there was frequent occurrence of guttation, from the time of emergence and throughout the sampling period (up to 65 days after emergence). Guttation was mainly observed in the early morning, and sometimes in the afternoon and in the evening. Overlapping of guttation occurrence and bee activity was always observed (up to several hours). The number of bees seen visiting the plants and collecting guttation fluids was limited. When observed, they were close to the hives. When alternative water sources were put close to the hives, the honey bees were observed to use mainly these as a source of water. However, the residue analysis of dead bees indicated the occurrence of an exposure. Moreover, in 2 out of 4 studies performed in France, mortality was higher than that in the control but no statistical analysis was carried out. As regards the effects on the colonies, no effects were observed on the colony strength, health, brood development or food storage.

Guttation of oilseed rape plants was a regularly occurring phenomenon during the autumn and spring growth period of the crop and there was usually a time overlap between the presence of guttation fluid and bee flight activity during morning hours. Honey bees were observed visiting the study plots frequently. The relative proportion of honey bees observed per monitoring on plants in the respective assessment areas, in both the treatment and control groups, was mostly higher in spring 2010 than in autumn 2009. Moreover, the observed relative proportion of honey bees per monitoring taking up guttation fluid and dew, in both the treatment and control groups, was also higher in all assessment zones in spring 2010 than compared to autumn 2009. Only a small proportion of bees were observed taking up guttation fluid. Regarding honey bee mortality, colony development in autumn and spring, and hibernation performance, no distinct differences were observed when comparing the performance of the treatment group with the performance of the control group.

Guttation occurrence was observed to be very limited in sugar beet. This was also reported in the EFSA, 2012a.

No studies were available for the other crops reported in Appendix A.

Several guttation experiments were conducted in Germany with clothianidin (Frommberger, M. *et al*., 2012; Pistorius, J. *et al*., 2012; Joachimsmeier *et al*., 2012) and were considered during the Pesticides Peer Review Experts' Meeting 97. The experiments were conducted with both seed treatment and granular products. The findings indicated that crops varied in the intensity and frequency of guttation events. Residues depended on the properties of the active substance, the quantity of the active substance per seed and other factors. Peak residues were observed in early growth stages. Guttation droplets were one out of several possible water sources in the area surrounding the colony and were only available for a limited time. Collection of guttation fluid was not an exposure scenario comparable with exposure from nectar and pollen. Risk is likely to decrease with the distance of the colonies from the treated crops and the availability of alternative water sources nearby. In the majority of realistic worst case exposure trials no treatment-related mortality peaks were observed, but frequently residues were detected in dead bees even when no increased mortality occurred. When colonies were placed directly next to the crop, on single days/rare occasions a clear increase in mortality was observed in some monitoring studies with maize. Overall, in the German experiments it was concluded that damage to the colonies in realistic worst case scenarios is at a low level, and effects on colony strength, brood development and overwintering were not observed. The relevance of exposure to guttation droplets was linked to the availability of other sources of water: it was noted that bees will collect guttation droplets significantly less where other alternative water sources are available.

Bees were not observed to collect guttation fluid from triticale and maize (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 further experiments within the APENET project (EFSA 2012c). For example Tapparo *et al.*, 2011 concluded that guttation is affected by several factors that cause a high variability both in intensity and in the residue levels, and therefore further experiments would be needed to understand the phenomenon and its consequence in the risk assessment. In Wallner *et al*., 2011, it is reported that consumption of guttation fluid contaminated with clothianidin led to a reduced colony development, however, in this experiment honey bees were forced to consume guttation fluid.

The experts at the Pesticides Peer Review Experts' Meeting 97 raised a concern over the suitability of effect field studies to address the potential risk to bees from exposure via guttation fluid. The experts considered that there are many influential parameters which are not yet fully understood (e.g. under what conditions bees are most likely to collect guttation fluid). Due to the fact that the studies are relatively new to regulatory risk assessment, there are no agreed study guidelines and there is only limited experience in their use for risk assessment. The experts therefore considered that there is some uncertainty as to the results of the available studies, and their relevance to all conditions in the EU.

2.3.3. Conclusion on the risk via systemic translocation – guttation

Potential exposure to guttation might lead to high risk to honey bees, due to the high residues detected in guttation droplets. For **maize**, the available studies sufficiently demonstrate that, under experimental conditions, even though guttation occurs frequently, bees were rarely observed collecting guttation fluid. Although there are questions about the long-term effects on colonies, which were not adequately studied, the experts concluded that since there is very little exposure, the risk may be considered low.

In the German experiments, overall, it was concluded that damage to colonies, in realistic worst case scenarios is at a low level, and effects on colony strength, brood development and overwintering were not observed. It was also reported that collection of guttation fluid was not an exposure scenario comparable with exposure from nectar and pollen. Risk is likely to decrease with the distance of the colonies from the treated crops and the availability of alternative water sources nearby.

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.

Overall, based on the available studies, and under the experimental circumstances they were performed, the risk from exposure via guttation was considered low for **maize**, **oilseed rape** and **sugar beet** seed treated with clothianidin. However, since guttation is a phenomenon that is dependent on crop and environmental conditions, further information is needed to extrapolate this outcome to other EU agricultural situations for the uses on maize, sugar beet and oilseed rape seed treatments. Therefore, a data gap is identified.

No specific data or information were available for the **other** authorised **uses** of clothianidin, therefore it was not possible to draw a conclusion. A data gap is concluded for information to address the 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) to honey bees from exposure via guttation fluid.

3. Risk assessments for granule products

Three granular formulation products are authorised in Member States under the names of 'Santana' and 'Cheyenne'. These formulations are intended to be applied in-furrow during the sowing of maize and sorghum. The application rates are in the range of 50 to 110 g a.s./ha.

3.1. Risk from contamination of adjacent vegetation via dust drift

3.1.1. First-tier acute, chronic and brood risk assessment

In line with the recommendations of EFSA 2012a, a first-tier acute risk assessment for honey bees may be performed for granular products 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, these calculations were not necessary in this case because they could be considered as covered by the first-tier risk assessment performed for the seed treatment uses (see Table 2). As reported in section 2.1.1, the HQ values were high and not sufficient to conclude a low risk for maize.

As for the seed treatment plant protection products, no information was available to perform a first-tier chronic and brood risk assessment (see sections 2.1.2 and 2.1.3).

3.1.2. Risk assessment using higher tier studies

No field studies investigating dust deposition were available for the granular products. Since the products are applied in-furrow during sowing, by using the same machinery, dust emission could not be excluded. A Heubach assay was conducted (Lindner, 2009, **study 34** and Krennhuber, 2009, **study 33** see Study evaluation notes; EFSA 2012d). Residues of clothianidin were found (converted in g a.s./100 kg granules) to range from 0.11 to 0.22 g a.s./100 kg granules following the analysis of filters and filter housings contaminated in the above mentioned Heubach assay. These values are below the values measured for maize seeds. It was noted at the Pesticides Peer Review Experts' Meeting 97 that Heubach values are considered to indicate the worst case scenario in relation to dust emission expected from the machinery used for the application of the granules. Since the application machinery is not the same as that used for the drilling the maize seed, the experts considered that dust generation during application of the granules was not of concern for bees foraging in adjacent areas (in the assessments conducted at Member State level for the product authorisation). Even if the granules cannot be considered 'dust-free', it was noted that the formulation 'Cheyenne' was considered to be 'dust-free' by the FR expert when they performed their assessment during product registration. This assessment was performed on the basis of the relevant data for dustiness, which were discussed during the Pesticides Peer Review Experts' Meeting 97 and made available to EFSA after the meeting.

Overall, on the basis of the information available, it was agreed that a low risk can be concluded for dust exposure, assuming that there is no air-flow in the application machinery when the granules are applied in the furrow. Assuming the same application technology, the same conclusion can be drawn for the authorised use in sorghum.

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

3.2.1. First-tier acute, chronic and brood risk assessment

Residue data on maize pollen were available for the formulated product 'Santana' (two residue trials, one performed in Italy and one in France). These data and the calculated RUD values, i.e. 0.065 - 0.1 mg/kg were reported in Appendix B. A first-tier risk assessment as described in section 2.2 was carried out, based on the highest RUD value, i.e. 0.1 mg/kg and the application rates reported in the GAP (Appendix A). The resulting ETR_{acute} were between 0.016 (application rate of 50 g a.s./ha) and 0.035 (application rate of 110 g a.s./ha). These values indicated that the potential exposure is lower than the toxicity. However, no trigger values are available for concluding on the risk assessment. It is also important to note that this assessment is based on limited residue data, and therefore it is uncertain. For example, the RUD value for the seed treatments, based on a more extensive data set, was notably higher than the RUD value for 'Santana'.

As regards the first-tier chronic and brood risk assessment, no specific calculations were carried out. However, the comparison between the chronic and larvae endpoints and the concentration in maize pollen, reported in sections 2.2.2 and 2.2.3 for the seed treatment products, also cover the granular products.

No data were available for sorghum. This crop can be considered attractive to honey bees for pollen and nectar according to the list compiled by the Netherlands (Ctgb, 2011), and therefore a data gap was identified for further information.

3.2.2. Risk assessment using higher tier studies

A multi-year study was performed with 'Santana' (Thompson 2011, **study 24;** see Study evaluation notes; EFSA 2012d). The study was conducted in France at three different sites. Bee monitoring and residue sampling was carried out. The bee monitoring included the observation of mortality at the bee hives and in the field, behaviour effects and condition of the colonies. Signs of disease were also investigated. Residues of clothianidin and metabolites were determined in maize pollen, pollen from traps, pollen from combs, bee pollen, wax and nectar. The highest value was found in pollen from traps (0.141 mg/kg). In the study it is concluded that “there were no detectable effects of exposure to clothianidin residues in maize pollen on the colony development in the 3 sites over the 3 years, with the greatest impact on colony survival being *Varroa* infestations in the southern and central sites”.

The study was well designed and reported results for several factors that may affect bee colonies. It showed several deficiencies, which made questionable the possibility to assess long-term effects taking into account several overwintering. Independently to the test item (the treated maize), the results indicated a high concern with regard to the colony health and long-term survival. However, care should be taken with the interpretation of these results. As regards *Varroa* infestations and other bee diseases, no background information was available for the normal bee health status. It is noted that, in the Member States where granular formulations are currently authorised, this study was considered useful to demonstrate a low acute and long-term risk to honey bees.

Overall, on the basis of the available information, it was not possible to draw a firm conclusion. Due to the lack of background information as regards what is normal colony survival rate under the conditions of the multi-year studies, further analysis of the available data would be needed in order to address the risk to honey bees (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 maize granular treatments. A data gap was therefore identified.

3.3. Risk via systemic translocation in plants – guttation

A study investigating guttation occurrence, residues and effects on bees was available for the formulated product ‘Santana’ (Thompson 2011, **study 9;** see Study evaluation notes; EFSA 2012d). In this study it was concluded that “the colonies experienced worst case exposure for 30 consecutive days with guttation for 28 days. There were no other significant sources of water available in and around the test fields (except for puddles after rain). Mortality was low throughout the exposure period although the treated colonies showed consistently slightly higher levels. Bee activity (bees leaving the hives) showed some overlap with the presence of guttation water on the crop although the peak periods of each did not coincide. Observations of bee activity on the maize crop (total of nearly 20 and 24 hours on the control and treated fields, respectively) showed very little bee presence. Only 9 and 20 bees, respectively, were seen resting or walking on the plants and only 2 bees in both cases were ever seen actually drinking guttation fluid. Colony assessments indicated that there was no impact of the treatment”.

Initially high levels of residues were found in the guttation fluid (9.1 mg/kg) and in dead bees (the 90^{th} percentile of residue detected in dead bees was 12 µg/kg). Since it was not excluded that the residues detected in dead bees were not linked to exposure via guttation, the study could not be considered useful to address the risk from guttation. In the guttation experiments performed in Germany on maize, it was noted that granular formulations gave the same level of residues in guttation droplets as seed treatment products, but with indications of a delay. Therefore, the same conclusion, as reported in section 2.3.3, could be drawn.

No data were available for sorghum, therefore a data gap has been identified.

3.4. Conclusion on the risk for granular products

Overall, as regards dust exposure, a low risk was concluded for granular formulations authorised for use in **maize** and **sorghum**, assuming that there is no air-flow in the application machinery when the granules are applied in the furrow. However, as regards the risk following exposure via residues in nectar and/or pollen and from exposure via guttation, on the basis of the available data it was not possible to draw a firm conclusion and data gaps were concluded.

4. Monitoring data

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

4.1. 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. Equally, 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 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.

4.2. 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). 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.

4.3. 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 honey bee 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, 2012a). The project started in 2011 and will end in June 2013. No further data are available.

Following the use of 'Santana' granules

The monitoring data summarise 8 reports of samplings from Lombardy (5 from Cremona district, 1 from Pavia district and 2 from Brescia district) in summer 2012 (Italy, 2012b). These data were submitted during the Pesticides Peer Review Experts' Meeting 97 meeting.

The depopulation phenomena (20 – 70 % decrease in bee numbers), declared by the beekeepers, were registered in July except for the sampling from the Brescia district, which was observed in August. The colony losses in July coincided with the spray application of products on maize crops (distance hive/maize crops: approximately 1.5 km) for the treatment of corn rootworm and corn borer, as claimed by beekeepers. Only in one report (in Cremona district), a beekeeper in a following interview declared that no spray application treatments were performed on maize, but the granular product 'Santana' was applied during the sowing period (April, May and June). In this case, a residue level of clothianidin of 0.407 mg/kg was detected in a maize inflorescence sample. No residues (either neonicotinoids or pyrethroids) were detected in honey comb samples above the LOD, i.e. 5 µg/kg. However, the experts noted that such a LOD is quite high, indicating uncertainty with the results. Some dead bee analyses indicated the presence of the Deform Wing Virus (DWV). In two reports also sublethal effects (nervous symptomatology) or behavioural abnormalities were recorded, such as homing failure or disorientation.

4.4. Monitoring data from France

Monitoring data for thiamethoxam ('Cruiser') from 2008 to 2010 in different regions of France were presented during the meeting. 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 be exposed to dust, guttation fluid and foraging on the flowering crop. Deflectors were introduced as mitigation measures in the last couple of 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 problematic to conduct such dedicated and targeted monitoring. In some samples thiamethoxam residues were detected in bee bread but this was before 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.

4.5. 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.

5. List of data gaps identified during the assessment

- Further information to address the risk to pollinators other than honey bees (relevant for all outdoor authorised uses; see section on 'Conclusions of the evaluation').

- Further information to address the risk to honey bees foraging nectar and/or pollen in succeeding crops (relevant for all outdoor authorised uses; 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 authorised uses; see section on 'Conclusions of the evaluation').

- Further information to address potential uptake via roots to flowering weeds (relevant for the authorised uses as granules; see section on 'Conclusions of the evaluation').

- Information to further address the potential dust exposure and hence the risk (i.e. the acute and long-term risk to colony survival and development, and the risk to bee brood). Relevant for the authorised uses as **seed treatments** on **maize** (the available higher tier data seem to exclude the risk to the colony, but some uncertainties were also indicated), **oilseed rape and barley** (the available higher tier studies might suggest a low exposure, however the available studies were performed in Germany with specific plant protection products and with application rates lower than some authorised uses), and **alfalfa, cereals other than barley, chicory, clover, mustard, sunflower and poppy** (no data available). (see section 2.1).

- Information to further address the risk following the ingestion of contaminated nectar and pollen, 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. Relevant for the authorised uses as **seed treatments** on **maize** (on the basis of the available higher tier data it was not possible to conclude) and for the other authorised uses in crops attractive to honey bees (for nectar and/or pollen), i.e. **alfalfa, clover, mustard, oilseed rape, sunflower and poppy** (no data or valid higher tier studies were available). Relevant also for the authorised uses of **granular products** in **maize** (a higher tier study was available but due to the lack of background information as regards a normal colony survival rate under the conditions of the multi-year studies, further data analysis is needed), and **sorghum** (no data available) (see sections 2.2, 3.2 and 3.4).

- Information to further address the potential guttation 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). Relevant for all authorised uses as **seed treatments** and **granules**. (For the uses as a seed treatment on maize, sugar beet and oilseed rape, under the experimental conditions, the available data indicated low exposure, but extrapolation to other EU agricultural situations would be needed. For the other crops no data were available) (see sections 2.3, 3.3 and 3.4).

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

- A low risk can be concluded for dust exposure for the granular products 'Santana' and 'Cheyenne' used in maize and sorghum, assuming that that there is no air-flow in the application machinery when the granules are applied in the furrow.

7. Concerns

7.1. 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 residues in exposure via guttation fluid. In addition, the risk to pollinators other than honey bees, the risk from 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 8.

7.2. Critical areas of concern

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

The risks identified are marked with an 'R' in the overview table in section 8. Risks have been 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 a higher tier study indicated a high risk.

8. Overview of the concerns identified for the authorised uses of clothianidin

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

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

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Cereals (wheat/ barley /oat /rye /triticale/durum wheat)	ARGENTO	BE	90	R	X				X	X	X	X	X
	Yunta Quattro	HU	100	R	X				X	X	X	X	X
	Redigo Deter	IE	110	R	X				X	X	X	X	X
	FS 373.4	RO	58.68	R	X				X	X	X	X	X
	Deter	CZ, UK	100	R	X				X	X	X	X	X
Chicory	PONCHO BETA	BE	69	X	X				X	X	X	X	X
Maize/ (sweet) corn/ forage maize/ grain maize	Poncho	AT	125	R	X	X	X	X	X	X	X	X	X
	FS 600 red	AT, RO	125	R	X	X	X	X	X	X	X	X	X
	FS 600 red	AT, RO, BG	50	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 to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Maize/ (sweet) corn/ forage maize/ grain maize	Poncho 600 FS	CZ	50	R	X	X	X	X	X	X	X	X	X
	PONCHO MAIS	BE	100	R	X	X	X	X	X	X	X	X	X
	PONCHO 600 FS	EL	41.7	R	X	X	X	X	X	X	X	X	X
	Poncho	ES	50	R	X	X	X	X	X	X	X	X	X
	Cheyenne**	FR	50			X[a]	X[a]	X[a]	X	X	X	X	X
	Poncho FS 600	HU	62.4	R	X	X	X	X	X	X	X	X	X
	Santana 1 G**	HU	110			X[a]	X[a]	X[a]	X	X	X	X	X
	PONCHO 600 FS ROSSO	IT	112.5	R	X	X	X	X	X	X	X	X	X
	Santana 0.7 GR**	IT	50			X[a]	X[a]	X[a]	X	X	X	X	X
	Santana 0.7 GR**	IT	80			X[a]	X[a]	X[a]	X	X	X	X	X
	Poncho Rood	NL	50	R	X	X	X	X	X	X	X	X	X
	Poncho	PT	47.0	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 to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Maize/ (sweet) corn/ forage maize/ grain maize	Poncho 600 FS	SK	25 g /2 years	R	X	X	X	X	X	X	X	X	X
	Poncho 600 FS	SK	62.4 g /4 yrs	R	X	X	X	X	X	X	X	X	X
	Poncho	UK	60	R	X	X	X	X	X	X	X	X	X
	TI-435 FS 600	COM rev. report	50	R	X	X	X	X	X	X	X	X	X
Mustard	Elado FS 480	CZ	50	X	X	X	X	X	X	X	X	X	X
	Modesto	CZ	25	X	X	X	X	X	X	X	X	X	X
Oilseed rape (winter / spring)	FS 480	AT	50	R	X	X	R	X	X	X	X	X	X
	Elado FS 480	CZ	60	R	X	X	R	X	X	X	X	X	X
	Modesto	CZ	30	R	X	X	R	X	X	X	X	X	X
	Elado (005849-00)	DE	50	R	X	X	R	X	X	X	X	X	X
	Modesto FS 480	DK	25	R	X	X	R	X	X	X	X	X	X
	Modesto	EE	70	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 to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Oilseed rape (winter / spring)	Modesto	EE	35	R	X	X	R	X	X	X	X	X	X
	Elado FS 480	FIN	80	R	X	X	R	X	X	X	X	X	X
	Ellado	HU	80	R	X	X	R	X	X	X	X	X	X
	Modesto	LT	30	R	X	X	R	X	X	X	X	X	X
	FS 480	LT, RO	30	R	X	X	R	X	X	X	X	X	X
	Modesto 480 FS	PL	25	R	X	X	R	X	X	X	X	X	X
	Elado 480 FS	SK	50 g /2 years	R	X	X	R	X	X	X	X	X	X
	Modesto	UK	30	R	X	X	R	X	X	X	X	X	X
Poppy	Poncho	AT	7.02	X	X	X	X	X	X	X	X	X	X
	Elado FS 480	CZ	22	X	X	X	X	X	X	X	X	X	X
Sugar beet/ fodder beet/ beet seeds	FS 453.34	AT, RO, IT	78						X	X	X	X	X
	PONCHO BETA	BE	72						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 to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Sugar beet/ fodder beet/ beet seeds	Poncho Beta FS 453.34	CZ	78						X	X	X	X	X
	Janus FS 180	CZ	13						X	X	X	X	X
	Janus (005505-00)	DE	13						X	X	X	X	X
	Poncho Beta (005495-00)	DE	78						X	X	X	X	X
	Poncho ungefärbt (025429-00)	DE	78						X	X	X	X	X
	Janus FS 180	DK	10						X	X	X	X	X
	Mondus FS 380	DK	10						X	X	X	X	X
	JANUS 180 FS	EL	15.4						X	X	X	X	X
	Poncho	ES	108						X	X	X	X	X
	Poncho Beta	FIN	60						X	X	X	X	X
	Poncho Beta	HU	60						X	X	X	X	X
	PONCHO 600 FS BIANCO	IT	90						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 to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Sugar beet/ fodder beet/ beet seeds	PONCHO BETA	IT	90						X	X	X	X	X
	FS 600 uncolored	IT	78						X	X	X	X	X
	Poncho Beta	NL	60						X	X	X	X	X
	Mundus 380 FS	PL	39						X	X	X	X	X
	Janus 180 FS	PL	10						X	X	X	X	X
	Janus 180 FS	SK	10						X	X	X	X	X
	Poncho 600 FS	SK	42 g /2 years						X	X	X	X	X
	FS 600 red	SI	78						X	X	X	X	X
	Poncho Beta	UK	78						X	X	X	X	X
	TI-435 FS 600	COM rev. report	78						X	X	X	X	X
Sorghum	Cheyenne**	FR	50			X[a]	X[a]	X[a]	X	X	X	X	X
Sunflower	Poncho 600 FS	SK	27	X	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 to honey bees from sublethal exposure	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 exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Sunflower	FS 600	RO	27	X	X	X	X	X	X	X	X	X	X
Alfalfa (minority use)	Elado FS 480	CZ	80	X	X	X	X	X	X	X	X	X	X
Clover (minority use)	Elado FS 480	CZ	60	X	X	X	X	X	X	X	X	X	X

Table compiled on the basis of Appendix A
** applied as granules
a: Potential exposure to honey bees from residues in nectar and pollen in flowering weeds

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APPENDICES

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

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
Cereals (wheat/ barley /oat /rye /triticale/durum wheat)	ARGENTO	BE	20 (?)	90	50 g a.s./100 kg	
	Yunta Quattro	HU	45	100	30-33.34 g/100 kg seeds	150-300 kg seeds/ha
	Redigo Deter	IE	90	110	500 g/t seeds	180-220 kg/ha
	FS 373.4	RO	48.01	58.68	26.67 g a.s./100 kg seeds	
	Deter	CZ, UK		100	0.5 g / kg seed	200 kg / ha
Chicory	PONCHO BETA	BE		69	30 g a.s./100 000 seeds	
Maize/ (sweet) corn/ forage maize/ grain maize	Poncho	AT	50	125		
	FS 600 red	AT, RO	87.5	125	62.5 g a.s./50 000 seeds	
	FS 600 red	AT, RO, BG	35	50	25 g a.s./50 000 seeds	25-50 kg/ha
	Poncho 600 FS	CZ		50	5 g a.s./10 000 seeds	max.100 000 seeds/ha
	PONCHO MAIS	BE		100	42 g a.s./50 000 seeds	
	PONCHO 600 FS	EL	37.5	41.7	0.5 mg a.s./seed	75 000-83 400 seeds/ha
	Poncho	ES	37.5	50	25 g a.s./50 000 seeds	75 000 - 100 000 seeds/ha
	Cheyenne**	FR		50	n/a	n/a
	Poncho FS 600	HU	25	62.4	25-62.4 g / 50 000 seeds	50 000 seeds/ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
Maize/ (sweet) corn/ forage maize/ grain maize	Santana 1 G**	HU		110	n/a	n/a
	PONCHO 600 FS ROSSO	IT	15	112.5		
	Santana 0.7 GR**	IT		50		
	Santana 0.7 GR**	IT		80		
	Poncho Rood	NL		50	0.5 mg a.s./seed	100 000 seeds/ha
	Poncho	PT		47.0	0.5 g a.s./seed	75 000-95 000 seeds/ha
	Poncho 600 FS	SK		25 g /2 years	25 g a.s./unit*	
	Poncho 600 FS	SK		62.4 g /4 years	62.4 g a.s./unit*	
	Poncho	UK		60	25.2 / 50 000 seeds	120 000 seeds / ha
	TI-435 FS 600	COM review report		50	0.5 mg a.s./seed	
Mustard	Elado FS 480	CZ		50	10 g a.s./ kg seeds	3-5 kg/ha
	Modesto	CZ		25	5 g a.s./ kg seeds	3-5 kg/ha
Oilseed rape (winter and spring)	FS 480	AT	45	50	10 g a.s./kg	3-5 kg/ha
	Elado FS 480	CZ		60	10 g a.s./kg	6 kg/ha
	Modesto	CZ	20	30	5 g a.s./kg	max. 5 kg/ha
	Elado (005849-00)	DE		50	25 ml/kg seed	max. 5 kg seeds/ha
	Modesto FS 480	DK		25		
	Modesto	EE		70	10 kg a.s./t seed	
	Modesto	EE		35	5 kg a.s./t seed	
	Elado FS 480	FIN	22.5	80	7.4-10 g a.s./kg seed	3-8 kg seeds/ha
	Ellado	HU	60	80	1000 g /100 kg seed	6-8 kg seeds/ha
	Modesto	LT	20	30	5 kg a.s./t seed	4-6 kg rape seed/ha
	FS 480	LT, RO	20	30	5 g a.s./kg	3-5 kg/ha
	Modesto 480 FS	PL	12.5	25	5 g a.s. /1 kg seeds	2.5-5 kg/ha
	Elado 480 FS	SK		50 g /2 years	1000 g a.s./100 kg seeds	5 kg seeds/ha
	Modesto	UK		30	5 g / kg seed	6 kg / ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
Poppy	Poncho	AT		7.02		
	Elado FS 480	CZ		22	22 g a.s./ kg seed	1 kg/ha
Sugar beet/ fodder beet/ beet seeds	FS 453.34	AT, RO, IT	60	78	60 g a.s./100 000 seeds	1.2-1.5 kg/ha
	PONCHO BETA	BE		72	60 g a.s./100 000 seeds	
	Poncho Beta FS 453.34	CZ	60	78	60 g a.s./100 000 seeds (=1 unit)	1.2-1.5 kg/ha (= 1 unit)
	Janus FS 180	CZ	10	13	10 g a.s./100 000 seeds (= 1 unit)	1.2-1.5 kg/ha (= 1 unit)
	Janus (005505-00)	DE		13	100 ml/ seedunit*	max. 1.3 seedunits*/ha
	Poncho Beta (005495-00)	DE		78	150 ml/ seedunit*	max. 1.3 seedunits*/ha
	Poncho ungefärbt (025429-00)	DE		78	100 ml/ seedunit*	max. 1.3 seedunits*/ha
	Janus FS 180	DK		10		
	Mondus FS 380	DK		10		
	JANUS 180 FS	EL	12.5	15.4	0.1 mg a.s./seed	125 000-155 000 seeds/ha
	Poncho	ES	54	108	45-60 g a.s./100 000 seeds	120 000-180 000 seeds/ha
	Poncho Beta	FIN	60	60	60 g a.s./100 000 seeds	
	Poncho Beta	HU		60	60 g/100 000 seeds	100 000 seeds/ha
	PONCHO 600 FS BIANCO	IT	45	90		1.2-1.5 unit*/ha
	PONCHO BETA	IT	36	90		1.2-1.5 unit*/ha
	FS 600 uncolored	IT	16	78	16-60 g a.s./100 000 seeds	
	Poncho Beta	NL		60	0.6 mg a.s./seed	100 000 seeds/ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min	g a.s./ha max	Seed dressing rate	Seed drilling rate (seed density rate)
Sugar beet/ fodder beet/ beet seeds	Mundus 380 FS	PL		39	30 g a.s. /seedunit*	1.3 seedunit*/ha
	Janus 180 FS	PL		10	10 g a.s./100 000 seeds	100 000 seeds/ha
	Janus 180 FS	SK		10	10 g a.s./unit*	
	Poncho 600 FS	SK		42 g/2 years	42 g a.s./unit*	
	FS 600 red	SI	16	78	16-60 g a.s./100 000 seeds	
	Poncho Beta	UK		78	60 g / 100 000 seeds	130 000 seeds / ha
	TI-435 FS 600	COM review report	19.5	78	0.15-0.6 mg a.s./seed	
Sorghum	Cheyenne**	FR		50		
Sunflower	Poncho 600 FS	SK		27	36 g a.s./unit*	max 0.75 unit*/ha
	FS 600	RO		27	5.4 g a.s./kg seed	
Alfalfa (minority use)	Elado FS 480	CZ		80	8 g a.s./kg	10 kg/ha
Clover (minority use)	Elado FS 480	CZ		60	6 g a.s./kg	10 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
COM = European Commission

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

formulation	dose g a.s/ha	crop	site	matrix	residue (mg a.s/kg) max	RUD	Authors	date	study ID
Poncho Pro	62.5	maize	DE	pollen maize	0.0104	0.166	Staedtler T./R. Schöning, M. Telscher	2008/09	M-309823-02-1
Poncho Pro	62.5	maize	DE	pollen from traps	0.0114	0.182	Staedtler T.	2009	M-309823-02-1
Clothianidin FS 600	45	maize	DE	pollen maize	0.0018	0.040	Ch. Maus et al	2005	E 319 2902-6
Clothianidin FS 600	45	maize	DE	pollen maize	0.0019	0.042	Ch. Maus et al	2005	E 319 2902-6
Clothianidin FS 600	-	maize	DE	pollen maize	< LOQ	-	Ch. Maus et al	2005	E 319 2902-6
Clothianidin FS 600	45	maize	DE	pollen maize	0.0012	0.027	Ch. Maus et al	2005	E 319 2903-7
Clothianidin FS 600	-	maize	DE	pollen maize	0.0013	-	Ch. Maus et al	2005	E 319 2903-7
Clothianidin FS 600	45	maize	DE	pollen maize	<LOQ	-	Ch. Maus et al	2005	E 319 2903-7
TI-435 FS 600	53.8	maize	DE	pollen	0.0054	0.100	Ch. Maus et al	2002f	E319 1840-5
TI-435 FS 600	53.8	maize	DE	pollen	0.0062	0.115	Ch. Maus et al	2001	E319 1835-0

formulation	dose g a.s/ha	crop	site	matrix	residue (mg a.s/kg) max	RUD	Authors	date	study ID
TI-435 FS 600	51.4	maize	DE	pollen	0.0029	0.056	Ch. Maus et al	2002b	E 370 2054 - 1
TI-435 FS 600	51.4	maize	DE	pollen	0.0021	0.041	Ch. Maus et al	2002c	E 370 2055 - 2
TI-435 FS 600	127.4	maize	DE/FR	pollen	0.015	0.118	R. Schöning	2005	M-243318-01-2
TI-435 FS 600	47.7	maize	FR	pollen	0.002	0.042	R. Schöning	2005	M-255328-01-2
TI-435 FS 600	47.5	maize	FR	pollen	0.014	**0.295**	R. Schöning	2005	M-255328-01-2
Santana[1]	122.56	maize	FR	pollen	0.008	0.065	M. Dilger	2011	20071122/El-FPMA
Santana[1]	110	maize	IT	pollen	0.011	0.100	M. Dilger	2011	S09-00346
clothianidin FS 600B G	0.5 mg a.s./seed	maize	FR[2]	pollen	0.004	0.008	Classen C.	2009	M-347727-01-1
clothianidin FS 600B G	0.5 mg a.s./seed	maize	FR[3]	pollen	0.006	0.012	Classen C.	2009a	M-347742-01-1
clothianidin FS 600B G	0.5 mg a.s./seed	maize	FR [4]	pollen	0.003	0.006	Classen C.	2009b	M-347748-01-1
TI-435 FS 600	25.6	sunflowers	DE	nectar	<0.0003	**0.012**	Ch. Maus et al	2001d	E319 1838-3
TI-435 FS 600	25.6	sunflowers	DE	pollen	0.0031	**0.122**	Ch. Maus et al	2001d	E319 1838-3
TI-435 FS 600	25.6	sunflowers	DE	nectar	<0.0003	0.012	Ch. Maus et al	2001e	E319 1837-2
TI-435 FS 600	25.6	sunflowers	DE	pollen	0.0029	0.114	Ch. Maus et al	2001e	E319 1837-2

formulation	dose g a.s/ha	crop	site	matrix	residue (mg a.s/kg) max	RUD	Authors	date	study ID
Clothianidin FS 600	90[5]	summer rape	DE	pollen	0.004	0.044	Ch. Maus et al	2007	E 319 2811-5
Clothianidin FS 600	90[5]	summer rape	DE	nectar	0.0022	0.024	Ch. Maus et al	2007	E 319 2811-5
Clothianidin FS 600	90[5]	summer rape	DE	pollen	< LOQ	-	Ch. Maus et al	2007	E 319 2811-5
Clothianidin FS 600	90[5]	summer rape	DE	nectar	< LOQ	-	Ch. Maus et al	2007	E 319 2811-5
TI-435 FS 600	28.4	summer rape	DE	nectar	0.003	0.106	Ch. Maus et al	2001b	E319 1839-4
TI-435 FS 600	28.4	summer rape	DE	nectar	0.0054	0.190	Ch. Maus et al	2001c	E319 1836- 1
TI-435 FS 600	28.4	summer rape	DE	pollen	0.0025	0.088	Ch. Maus et al	2001c	E319 1836- 1
TI435 FS 600	43	summer rape	SW	nectar	0.0086	**0.200**	R. Schmuck, R. Schoning	2000	E 370 1361-1
TI435 FS 600	43	summer rape	SW	blossoms	0.0041	0.095	R. Schmuck, R. Schoning	2000	E 370 1361-1
TI435 FS 600	51	summer rape	UK	blossoms	0.0033	0.065	R. Schmuck, R. Schoning	2000	E370 1357-6
TI435 FS 600	51	summer rape	FR	pollen	0.0017	0.033	R. Schmuck, R. Schoning	2000	E370 1359-8
TI435 FS 600	51	summer rape	FR	nectar	<0.001	-	R. Schmuck, R. Schoning	2000	E370 1359-8
TI435 FS 600	51	summer rape	FR	blossoms	<0.001	-	R. Schmuck, R. Schoning	2000	E370 1359-8

formulation	dose g a.s/ha	crop	site	matrix	residue (mg a.s/kg) max	RUD	Authors	date	study ID
-	90[5]	winter rape	DE	pollen	0.001	0.011	Ch. Maus et al	2007	E 319 3027-5
-	90[5]	winter rape	DE	nectar	< LOQ	-	Ch. Maus et al	2007	E 319 3027-5
-	90[5]	winter rape	DE	nectar	< LOQ	-	Ch. Maus et al	2007	E 319 3028-6
TI-435 FS 600	48.9	winter rape	DE	nectar	<LOQ	-	Ch. Maus et al	2002a	E 319 1916-0
TI-435 FS 600	48.9	winter rape	DE	pollen	<LOQ	-	Ch. Maus et al	2002a	E 319 1916-0
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	52.3	winter rape	DE	pollen	0.0031	0.059	A. Nikolakis et al	2011	M-412082-01-1
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	52.3	winter rape	DE	nectar	<0.001	-	A. Nikolakis et al	2011	M-412082-01-1
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	50	winter rape	DE	pollen	0.0016	0.032	A. Nikolakis et al	2012	M-421561-01-1
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	50	winter rape	DE	nectar	<0.001	-	A. Nikolakis et al	2012	M-421561-01-1
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	50.38	spring rape	DE	pollen	0.0066	0.131	A. Nikolakis et al	2012	M-421571-01-1
Elado® (clothianidin + beta-cyfluthrin FS 480	50.38	spring rape	DE	nectar	0.0016	0.032	A. Nikolakis et al	2012	M-421571-01-1

formulation	dose g a.s/ha	crop	site	matrix	residue (mg a.s/kg) max	RUD	Authors	date	study ID
(400+80) G;									
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	50.38	spring rape	DE	pollen	0.012	**0.238**	A. Nikolakis et al	2012	M-421580-01-1
Elado® (clothianidin + beta-cyfluthrin FS 480 (400+80) G;	50.38	spring rape	DE	nectar	0.0017	0.034	A. Nikolakis et al	2012	M-421580-01-1

Value in **bold** used for risk assessment. LOQ=0.001 mg/kg; LOD=0.0003 mg/kg
[1] Granular formulation to be incorporated in soil;
[2] Alsace;
[3] Languedoc-Roussillon;
[4] Champagne;
[5] Soil treatment; Residue related to following crop

ABBREVIATIONS

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

OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
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