CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance thiacloprid

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State the United Kingdom and co-rapporteur Member State Germany for the pesticide active substance thiacloprid are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of thiacloprid as an insecticide on oilseed rape foliar use and maize seed treatment. The peer review also provided conclusions on whether exposure of humans to thiacoprid can be considered negligible, taking into account the European Commission's draft guidance on this topic. Confirmatory data following the review of existing maximum residue levels (MRLs) according to Article 12 of Regulation (EC) No 396/2005 were also assessed in this conclusion. The reliable end points, appropriate for use in regulatory risk assessment are presented. An evaluation of data concerning the necessity of thiacloprid as an insecticide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods is presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: thiacloprid, peer review, risk assessment, pesticide, insecticide

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Thiacloprid is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), United Kingdom, and co-rapporteur Member State (co-RMS), Germany, received an application from Bayer CropScience AG for the renewal of approval of the active substance thiacloprid. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Germany), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

Thiacloprid has a harmonised classification and labelling as carcinogen category 2 and toxic for reproduction category 1B. The substance meets the cut-off criteria for non-approval, Annex II, Point 3.6.4 of Regulation (EC) No 1107/2009 (Repro 1B). The applicant provided under the renewal of the approval further information to demonstrate that the exposure of humans to thiacloprid was negligible under realistic conditions of use. Thiacloprid is therefore being assessed under the provisions of negligible exposure to satisfy points 3.6.3 and 3.6.4 of Annex II of Regulation 1107/2009. Furthermore, the applicant requested a derogation under Article 4(7) of Regulation (EC) 1107/2009, submitting evidence regarding the necessity of thiacloprid to control a serious danger to plant health. The evaluation of the concerned data is presented in the Appendices B and C to this conclusion.

The RMS provided its initial evaluation of the dossier on thiacloprid in the renewal assessment report (RAR), which was received by EFSA on 31 October 2017. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Bayer CropScience AG, for comments on 23 January 2018. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 27 March 2018.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether thiacloprid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of thiacloprid as an insecticide on oilseed rape and maize as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

The use of thiacloprid according to the representative uses proposed at the European Union (EU) level results in a sufficient insecticidal efficacy against the target organisms.

A data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites in the mammalian toxicology area since it was considered insufficient to conclude whether relevant published literature may have been missed due to the stringent criteria used to assess the relevance of the published literature.

In the section identity, physical/chemical properties, analytical methods data gaps were identified for information on the identity of polymeric co-formulants; for monitoring methods for M29, M30, M34 and M46 in surface water and M30, M34 and M46 in ground water; and for monitoring method for M07 in body fluids and tissues.

In the mammalian toxicology area, since the comparative *in vitro* interspecies metabolism study provided was found unreliable, the need for further tests and risk assessment to unique human metabolites could not be finalised. The criteria for approval are not met for thiacloprid according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009 since the harmonised classification of the active substance includes toxic for reproduction category 1B (Repro 1B), unless the exposure of humans to that active substance, under realistic proposed conditions of use is negligible, therefore control measures and personal protective equipment have been taken into consideration to minimise non-dietary exposure to the active substance. Estimated acute operator exposure showed an exceedance of the acute acceptable operator exposure level (AAOEL) in one of the three seed treatment plants studied where the operator used compressed air during cleaning of the treatment chamber, while showing a much lower exposure in the other two plants where this practice was not followed.

The assessment in the residues section is provisional with regard to unfinalised assessments for primary oilseed crops, rotational crops and the potential transfer of residues in animal commodities. Although with the available data for the representative uses concentrations of thiacloprid < 0.01 mg/kg could be demonstrated in food and feed items, it might be surmised that concentrations of thiacloprid metabolites in food items (rotational crops) and feed items could exceed this level.

The assessment of confirmatory data identified during the maximum residue level (MRL) review (Art. 12) resulted in the conclusion that the requirement for a maize metabolism study and a monitoring method for tea fermented leaves are fulfilled.

The data available on environmental fate and behaviour were sufficient to carry out the required environmental exposure assessments at the EU level for the representative uses, with the notable exception that a data gap was identified for information on the effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface, when surface water is abstracted for drinking water. This gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses. The potential for groundwater exposure (estimated as 80th percentile annual average recharge concentrations moving below 1 m) above the parametric drinking water limit of 0.1 μg/L consequent to the representative uses, was assessed as high for soil metabolites M30, M34 and M46 in geoclimatic situations represented by all the pertinent FOCUS groundwater scenarios. These three metabolites have been concluded as relevant groundwater metabolites. This results in the identification of a critical area of concern.

In the area of ecotoxicology, no critical areas of concerns were identified. However, the risk assessment for birds and mammals from the relevant plant metabolites, the risk assessment for aquatic organisms, the risk assessment for bees and the risk assessment for terrestrial non-target plants could not be finalised.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[2]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of up to 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS United Kingdom and co-RMS Germany received an application from Bayer CropScience AG for the renewal of approval of the active substance thiacloprid. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Germany), the European Commission and EFSA about the admissibility.

Thiacloprid has a harmonised classification and labelling as carcinogen category 2 and toxic for reproduction category 1B. The substance meets the cut-off criteria for non-approval, Annex II, Point 3.6.4 of Regulation (EC) No 1107/2009 (Repro 1B). The applicant provided under the renewal of approval further information to demonstrate that the exposure of humans to thiacloprid is negligible under realistic conditions of use. Thiacloprid is therefore being assessed under the provisions of negligible exposure to satisfy points 3.6.3 and 3.6.4 of Annex II of Regulation 1107/2009. The European Commission had clarified that taking into account the absence of a final guidance document and ongoing discussions in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), the draft guidance document on assessment of negligible exposure (draft dated May 2015; SANCO/2014/12096 (European Commission, 2015)) should be considered. Furthermore, the applicant also requested derogation under Article 4(7) of Regulation (EC) 1107/2009, by submitting evidence regarding the necessity of thiacloprid to control a serious danger to plant health. Further details on the process of evaluation of the concerned data and the related outcome are presented in the Appendices B and C to this conclusion

The RMS provided its initial evaluation of the dossier on thiacloprid in the RAR, which was received by EFSA on 31 October 2017 (United Kingdom, 2017).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Bayer CropScience AG, for consultation and comments on 23 January 2018. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 27 March 2018. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 11 May 2018. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

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

consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November–December 2018.

In line with the provisions of Article 4(7) of Regulation (EU) 1107/2009, on 22 November 2017, the applicant forwarded to the EMS and EFSA a submission for derogation regarding the necessity of thiacloprid to control a serious danger to plant health which cannot be contained by other available means, consisting in a data collection set and a report (Bayer CropScience, 2017). The applicant included claims that the use of thiacloprid is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 in the following Member States: Austria, Belgium, Bulgaria, Croatia, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Romania Slovakia, Slovenia, Spain, Sweden and the United Kingdom. On 26 June 2018, EFSA launched a two-month commenting phase asking all MS to confirm that the uses for which the applicant requests Article 4(7) derogation are authorised and if the use of thiacloprid is considered essential to control the serious danger to plant health, giving clear justification for each use that is considered as critical. In addition, all Member State (MS) were invited to supplement the information provided by the applicant with information from their own MS uses also considering other uses not presented by the applicant (e.g. minor uses). During the commenting phase, 15 MS (Austria, Belgium, Bulgaria, Denmark, Finland, Germany, Greece, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Spain and the United Kingdom) validated the information provided by applicant.

As a follow up, EFSA ensured that the methodology was consistently applied by MS and summarised the evaluation of thiacloprid (See Appendices B and C) in the current report. A final consultation process on the draft Appendices was launched in November 2018.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of thiacloprid as a foliar applied insecticide on oilseed rape and as seed treatment on maize as proposed by the applicant. Confirmatory data following the review of existing maximum residue levels (MRLs) according to Article 12 of Regulation (EC) No 396/2005[3] were also assessed. A list of the relevant end points for the active substance and the formulation and the proposed MRLs is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report 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 comments received on the RAR;
- the reporting table (11 May 2018);
- the evaluation table (14 December 2018);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (United Kingdom, 2018), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

The active substance and the formulated product

Thiacloprid is the ISO common name for {(*Z*)-3-[(6-chloro-3-pyridyl)methyl]thiazolidin-2-ylidene} cyanamide (IUPAC).

The representative formulated products for the evaluation were 'Thiacloprid OD 240', an oil dispersion (OD) containing 240 g/L thiacloprid and 'Thiacloprid FS 400', a flowable concentrate for seed treatment (FS) containing 400 g/L thiacloprid.

The representative uses evaluated were foliar spray applications for the control of *Meligethes aeneus, Ceutorhynchus napi, Ceutorhynchus quadridens* in oilseed rape and a seed treatment in maize for the control of wireworm and frit fly. Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of thiacloprid according to the representative uses proposed at the EU level result in a sufficient insecticidal efficacy against the target organisms, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

The assessment of the literature search in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011), performed by the applicant and summarised by the RMS, was considered insufficient to conclude whether relevant published literature may have been missed due to the criteria used to assess the relevance of the published literature, such as the requirement of the impurity profile of the test material; this was identified as a data gap; it is noted that the RMS considered the literature review as adequate.

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The proposed specification for thiacloprid is based on batch data from industrial plant production and quality control data. The proposed minimum purity of the technical material is 975 g/kg. The proposal is to maintain the current reference specification. It should be noted that the reference specification was not supported by data from one of the sources since two new relevant impurities were identified: methanol measured in the batches at maximum level of 0.63 g/kg and dimethylsulfate (DMS) not properly measured in the batches (see Section 2). Pending the decision on the reference specification, analytical methods for determination of DMS in technical material, analytical methods for determination of relevant impurities in the formulations and information on the relevant impurities before and after storage of the formulations might be required. The batches used in the (eco)toxicological assessment support the proposed specification (See Sections 2 and 5). The manufactured technical material meets the requirements of the existing FAO specification (613/TC, May 2010, belonging to the material of Bayer CropScience) in terms of minimum purity, though relevant impurities are not specified in the FAO specification.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of thiacloprid or the representative formulations. However a data gap for information on the identity of polymeric co-formulants was identified. The main data regarding the identity of thiacloprid and its physical and chemical properties are given in Appendix A.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulations and for the determination of the respective impurities in the technical material.

Thiacloprid residue can be monitored in food and feed of plant origin by the modified Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. Thiacloprid residue in food of animal origin can be determined by the QuEChERS method using HPLC–MS/MS with LOQ of 0.01 mg/kg in all animal matrices.

Thiacloprid residues in soil and water can be monitored by HPLC–MS/MS with LOQs 2 μg/kg and 0.05 μg/L, respectively. However, residue definition for monitoring for surface water was concluded as thiacloprid, M29, M30, M34 and M46 and for groundwater thiacloprid and M30, M34 and M46 therefore data gap for monitoring methods for determination of M29 in surface water and M30 M34 and M46 in groundwater and surface water was identified. Appropriate high-performance liquid chromatography with ultraviolet (HPLC-UV) detection method exists for monitoring thiacloprid residue in air with a LOQ of 0.0018 mg/m^3.

The HPLC–MS/MS method based on QuEChERS can be used for monitoring of thiacloprid residues in body fluids (urine and blood) with LOQ of 0.05 mg/L. The thiacloprid residues in body tissues could be analysed by the method used for animal products. However, it was concluded that also M07 should be monitored in body fluids and tissues and as a consequence an analytical method for determination of M07 in body fluids and tissues is required (data gap).

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on dermal absorption (EFSA PPR Panel, 2012), Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014c) and Guidance on the Application of the CLP Criteria (ECHA, 2017), draft Technical Guidance Document on assessment of negligible exposure (European Commission, 2015).

Thiacloprid was discussed at the Pesticides Peer Review Teleconferences 191 and 196 in September 2018.

The technical specification from two sources is supported by the batches used in the toxicological studies unlike a third source that includes two new relevant impurities, DMS (harmonised classification as Muta 2, H341 'Suspected of causing genetic defects' and Carc 1B, H350 'May cause cancer' according to Annex VI of Regulation (EC) No 1272/2008[4] – CLP Regulation) and methanol (harmonised classification Acute Tox. 3, H311 'Toxic in contact with skin' and H331 'Toxic if inhaled', and STOT SE 1, H370 'Causes damage to organs') for which maximum concentration limits are established below 0.01% and at 3%, respectively (according to classification, labelling and packaging (CLP) Regulation). The analytical methods used in the toxicological studies were adequate at least for the key studies that were the basis of the toxicological reference values.

Thiacloprid is extensively absorbed after oral administration, metabolised and rapidly eliminated mostly through urine within 24 h. The residue definition for body fluids and tissues was established as thiacloprid and its major metabolite in urine, M07, but an analytical method was not available to monitor M07 in these matrices (see data gap Section 1). The comparative *in vitro* interspecies metabolism study provided was inadequate to conclude on the risk assessment to potential unique human metabolites since the results of the study did not correlate to the results obtained *in vivo*. This led to a data gap and an issue that could not be finalised.

In the acute toxicity studies, thiacloprid showed high, low and moderate acute toxicity when administered by the oral, dermal and inhalation routes respectively, resulting in harmonised classification as Acute Tox. 3, H301 'Toxic if swallowed' and Acute Tox. 4, H332 'Harmful if inhaled' according to the CLP Regulation. Thiacloprid is negative for phototoxicity following *in vitro* phototoxicity testing; however, the test is not considered appropriate to investigate ultraviolet B (UVB) absorbers such as thiacloprid. It should however be noted that no validated method is currently available to properly investigate UVB absorber chemicals and this applies to both phototoxicity and photomutagenicity end points (data gap).

Following short- and long-term oral administration in rat, mouse and dog, thiacloprid showed target organ toxicity in the liver; in dogs prostate toxicity was also observed. The relevant short-term no-observed adverse effect level (NOAEL) is 7 mg/kg body weight (bw) per day from the 90-day study in rat. Upon long-term exposure in rats, in addition to the liver, effects were also observed in the thyroid, eye, nervous system and muscles whereas in mice effects were observed in addition to the liver in the adrenals, lymph nodes and ovaries. The relevant long-term NOAEL is 1.2 mg/kg bw per day from the 2-year study in rats. Neoplasias were observed in both rats (uterine adenocarcinomas and thyroid follicular cell adenomas) and mice (benign ovarian luteomas) with a relevant carcinogenic NOAEL of

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

2.5 mg/kg bw per day from the 2-year study in rats and lowest observable adverse effect level (LOAEL) of 11 mg/kg bw per day in the 18-month carcinogenicity study in mice. The RMS considered 11 mg/kg bw per day as a NOAEL of the study and the benign ovarian luteoma relevant only at the higher dose levels.[5] Accordingly, a harmonised classification as Carc. 2 (H351 'Suspected of causing cancer') was established in the CLP Regulation (ECHA, 2015). From the evaluation of negative *in vitro* and *in vivo* genotoxicity studies, the active substance is unlikely to be genotoxic. A definite mode of action (MoA) for the tumour formation was not demonstrated but uterine and ovarian tumours may have resulted from an endocrine-mediated MoA; thyroid tumours were a consequence of liver enzyme induction, but human relevance of these tumours could also not be excluded.

In one- and two-generation reproductive toxicity studies in rats, increased incidence of dystocia was consistently observed, leading in some cases to the death of dams and reduced pup weight and viability. The resulting NOAEL is 2.7 mg/kg bw per day for the reproductive and offspring's toxicity. The parental NOAEL was established at the same dose level of 2.7 mg/kg bw per day based on reduced body weights, increased thyroid and liver weights with histological correlates of hepatocyte and thyroid follicular hypertrophy. Ovarian aromatase activity was increased in pregnancy and remained elevated during lactation. Alteration of sex hormone levels was proposed as the MoA for dystocia; however, a causal relationship for this MoA was not demonstrated. The relevance to humans of these effects could not be ruled out. In a developmental toxicity study in rats, the developmental NOAEL was set at 2 mg/kg bw per day based on increased incidence of pelvic dilation and skeletal variations in fetuses in the absence of maternal toxicity (maternal NOAEL 10 mg/kg bw per day). The RMS did not agree with the setting of a developmental NOAEL at 2 mg/kg bw per day, considering that the effects on renal pelvis dilation, although treatment-related, should not be considered adverse.[6] In rabbits, the maternal and developmental NOAELs were also set at 2 mg/kg bw per day based reduced maternal and fetal weight. Higher dose levels resulted in post-implantation losses in both rats and rabbits. With regard to reproductive and developmental toxicity, harmonised classification as Repro 1B, H360FD has been established (ECHA, 2015). Reduced body weight (in dams and pups) as well as delayed sexual maturation but no signs of developmental neurotoxicity were observed in a developmental neurotoxicity study in rats. In an acute neurotoxicity study, alteration of motor and locomotor activity were observed, leading to the harmonised classification as STOT SE 3, H336 'May cause drowsiness or dizziness'. No neurotoxic effects were observed upon repeated dose neurotoxicity testing. Immunological investigations performed in the 90-day toxicity study in rats revealed a slight increase in macrophage activation and mitogenic stimulation at the highest dose tested.

EFSA considers that an endocrine disruptor (ED) assessment in line with current guidance for the identification of EDs in the context of Regulation (EU) No 1107/2009 is not necessary for thiacloprid (ECHA and EFSA, 2018) since the non-inclusion criteria are already met with the harmonised classification as Repro 1B for thiacloprid. It is however noted that thiacloprid was considered to meet the EFSA Scientific Committee (2013) criteria and WHO definition for an ED as it causes adverse effects on the reproductive and endocrine system through an endocrine MoA.

Toxicological data have been provided on groundwater and plant metabolites of thiacloprid, the outcome is reported in the Appendix A. It was concluded that the groundwater metabolites **M30**, **M34** and **M46** are relevant according to the guidance document on the assessment of the relevance of metabolites in groundwater (European Commission, 2003) since it cannot be excluded that these metabolites share the carcinogenic properties of the parent thiacloprid (see Section 4). Regarding metabolites that may be found at significant levels in residues, **M01**, **M02**, **M03**, **M30**, **M34** and **M37** (see Section 3), they are unlikely to be genotoxic, they are considered of low acute toxicity after oral administration (except M01 and M37 for which no acute toxicity data were provided, only *in silico* analysis of their genotoxic potential) and it cannot be excluded that they share the carcinogenic potential of the parent (in the case of M03, the metabolite was found to be a major rat metabolite of the a.s. acetamiprid, was therefore considered covered by the toxicological profile, including carcinogenicity potential of acetamiprid). M01, M02 and M37 may also share the reproductive toxicity potential of the parent while for M30 and M34, this is unlikely.

The acceptable daily intake (ADI) of thiacloprid is 0.01 mg/kg bw per day[7] based on the NOAEL of 1.2 mg/kg bw per day for liver histopathology and eye effects from the 2-year rat study and applying a standard uncertainty factor (UF) of 100.

[5] See experts' consultation 2.3 in the Report Pesticides Peer Review TC 191.
[6] See experts' consultation 2.4 in the Report Pesticides Peer Review TC 191.
[7] No changes of the ADI value with regards to the previous review (European Commission, 2004).

The acceptable operator exposure level (AOEL) is 0.02 mg/kg bw per day[8] based on the NOAEL of 2 mg/kg bw per day for decreased maternal and fetal weight from the developmental toxicity study in rabbits; this NOAEL was supported by the rat developmental toxicity study for increased incidence of pelvic dilation and skeletal variations. No correction for oral absorption was needed and an UF of 100 was applied.

The acute acceptable operator exposure level (AAOEL) and acute reference dose (ARfD)[9] are 0.02 mg/kg bw based on the NOAEL of 2 mg/kg bw per day for developmental effects in the rat developmental toxicity study and applying an UF of 100.

First-tier negligible assessment of non-dietary exposure

Regarding the representative formulations, 'Thiacloprid OD 240', the non-dietary exposure assessments were performed according to the EFSA calculator (EFSA, 2014c) using dermal absorption values of 0.2% for the concentrate formulation and 14% for the in-use spray dilution. Control measures and personal protective equipment (PPE) have been taken into consideration to minimise operator exposure as reported in the Appendix A. Regarding the tractor-mounted applications of Thiacloprid OD 240 in oil seed rape, calculated operator exposure can be minimised to 1.1% of the AAOEL when closed transfer system during loading (CTS), drift reduction nozzles and PPE such as gloves during application are considered. Worker exposure represents 7.6% of the AOEL when no specific PPE, but workwear is considered; worker exposure can be minimised to 1.9% of the AOEL if re-entry restrictions of 3 days are introduced. Bystander and residents' exposure are estimated to remain below 10% of the (A)AOEL if drift reduction nozzles are applied.

Regarding Thiacloprid FS 400 uses as seed treatment to maize, estimated acute operator exposure exceeded AAOEL (103.9%) in one of three seed treatment plant studied while showing a much lower exposure (up to 0.8% of the AAOEL) in the other two plants studied. It was considered likely that the higher level of exposure in the later plant was due to the use of compressed air whilst cleaning the treatment chamber causing a cloud of dust; compressed air was not used by the operators in the other two treatment plants when cleaning the treatment chamber. It was therefore considered that the use of compressed air during cleaning operations should not be allowed in order to reduce exposures to operators undertaking cleaning operations and also to reduce the background levels of exposure in seed treatment plants from air borne dust generated when using compressed air. Worker exposure is estimated to represent up to 3.4% of the AAOEL, and reduced to 1.2% of the AAOEL if RPE is used during loading. Bystander and residents' exposure during sowing of seeds remain below 0.1% of the (A)AOEL.

Second-tier negligible assessment of non-dietary exposure

A second-tier negligible exposure assessment should reflect the margin of exposure (MoE) between the non-dietary exposure and the NOAELs established for the critical effects leading to the hazard cut-off criterion met (Repr. 1B for effects on fertility and development). The adverse effects on sexual function and fertility relate to dystocia and the adverse effects related to development increases in post-implantation losses, decreased pup viability and decreased pup weights (ECHA, 2015). Since the overall NOAELs for these effects were used to set the toxicological reference values, a refined negligible exposure assessment using hazard specific NOAELs is not possible.

3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on MRL calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2011) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

Thiacloprid was discussed at the Pesticides Peer Review meeting 184 and at the Pesticides Peer Review Teleconference 197 in September–October 2018.

3.1. Representative use residues

Primary crop metabolism studies with foliar treatment are available on crops from four different crop categories: fruit (apples and tomato), pulses/oilseeds (cotton), root crops (potato) and cereals

[8] No changes of the AOEL value with regards to the previous review (European Commission, 2004).
[9] The ARfD value in the previous review was 0.03 mg/kg bw (European Commission, 2004).

(wheat). Seed treatment and soil treatment uses were addressed by additional studies in the crop categories of cereals (maize, rice) and pulses and oilseeds (sunflower). Labelling was either on the thiazolidine or methylene rings, the only exception being seed-treated maize where both labels were used. There is evidence of extensive cleavage of the parent ring structure in several of the tested commodities. Therefore, despite of the diverse metabolism studies available, metabolism in plant cannot be considered fully addressed. As regards the representative uses primary crops, additional information that addresses the fate of thiacloprid in oilseeds with regard to the formation of metabolites from the thiazolidine moiety is necessary (data gap). For uses other than the representative uses, it should be considered whether the available metabolism data are sufficient. Therefore, the peer review took into account just the crop categories relevant to the representative uses.

In seed-treated maize, M01 (free and conjugated) was the major residue in forage (49–56% total radioactive residue (TRR)) and stover (45–61% TRR). Thiacloprid was still present as a significant residue (forage 16–21% TRR, stover 8–17% TRR) and was moreover identified in maize pollen (26–28% TRR), indicating that thiacloprid is translocated from the treated seed into aerial parts of the plant. In maize kernels, thiacloprid was not detected while M03 was tentatively identified, representing 26% TRR but the levels were < 0.01 mg/kg. In foliar-treated wheat, thiacloprid was predominant in hay (81% TRR), grain (81% TRR) and in straw (83% TRR). The rice metabolism study (application to soil prior to flooding) is not sufficiently representative of the current uses and showed a different metabolic pattern with M02 as major residue in rice forage (20% TRR) and grain (13% TRR) and M29 as unique metabolite.

In foliar-treated cotton, thiacloprid was identified in leaves (89% TRR) and gin trash (73% TRR), but was < 1% TRR in cotton seeds whilst M03 (free and conjugated) amounted to about 76% TRR (0.84 mg/kg). In the seeds of seed-treated sunflower, the residues of thiacloprid were very low (6% TRR, < 0.01 mg/kg) while M03 (free and conjugated) was found at 19% TRR (0.03 mg/kg).

The **plant residue definition for monitoring** is proposed as 'thiacloprid'.

For **risk assessment** purposes the **residue definition** is proposed as follows: For **cereals** (except rice) as 'thiacloprid' only and for **oilseeds**, provisional and pending availability of the requested data and information on metabolism, as 'thiacloprid and M03 (free and conjugated)'. The abundance of M01 (free and conjugated) residues in cereal feed items is noted (up to 61%TRR), and residue above the LOQ of this compound (0.04 mg/kg at N rate) are expected. It cannot be excluded that M01 shares the toxicological properties of thiacloprid (see Section 2). However, considering the representative uses, livestock dietary exposure is not expected to lead to significant residue transfer into animal commodities and it was therefore proposed not to include M01 in the residue definition.

A confined rotational crop study (with the methylene label only) in leafy, root and cereal crops indicated that uptake of residues from soil can be significant, this is in the context that metabolites M02, M30 and M29 formed from thiacloprid in soil, exhibited high and very high soil persistence, M34 exhibited moderate soil persistence (see Section 4). As pointed out for primary crops with regard to missing information on the fate of the thiazolidine moiety, consideration might have to be given whether the nature of residues in rotational crops can be considered sufficiently addressed (data gap). Thiacloprid has never been identified in any crop part. Metabolites M02, M30, M34, M36, M37 are recovered at significant proportions (largely exceeding 10% TRR) in rotational crops. Consideration of the expected residue concentrations in the different commodities were made, taking into account soil plateau concentrations. M36 was not considered significant in any commodity (< 0.01 mg/kg) and M34 only in cereal crops (grain 0.01, 0.02–0.13 mg/kg in feed items), provided thiacloprid is applied in compliance with the requested GAP for the representative uses.

In rotational crops, residue levels of M37 ≥ 0.01 mg/kg might be reached for leafy crops at short plant-back intervals (30 days). For M37, the toxicological data are insufficient (see Section 2) and it cannot be excluded that M37 shares the toxicological properties of thiacloprid. Therefore, either the relevant toxicity of this compound should be ruled out or higher tier studies to refine the exposure assessment should be provided.

The proposed risk assessment residue definitions for **rotational crops** (provisional) are: 'Thiacloprid and M03' for **oilseeds**. 'Thiacloprid' by default for **leafy crops**, provided non-relevance of M37 can be demonstrated. 'Thiacloprid' by default for root **crops and cereals**, specifically for rotational feed items (tops of root crops, cereal forage, hay and straw). M02 and M30 might also have to be considered but further information is necessary to conclude, as detailed here below.

Metabolism studies in goat and hen are available with thiacloprid. The studies in poultry had shortcoming that made it of limited value for prediction of whether significant transfer of residues in

poultry matrices can be expected while the metabolic pattern in poultry upon exposure to thiacloprid can still be addressed on the basis of this study. However, as for the representative uses, thiacloprid does not drive the livestock burden; while estimated residues of M02 in rotational crops are expected to lead to a livestock burden exceeding the trigger value for ruminants and the same for residues of M30 in ruminants and poultry. It cannot be excluded that other uses than the representative uses could lead to significant animal exposure to thiacloprid, but this scenario was not assessed during the peer review. M30 is not an identified metabolite in the livestock metabolic pathway and metabolism of M30 is not expected to proceed via a common pathway with M02. Therefore, the residue behaviour of M30 in livestock and the potential residues in animal commodities cannot be accurately estimated and further information is necessary. Although M02 is also not identified in the livestock metabolism studies, the applicant proposed that M02 is an intermediate in the formation of M11 in both poultry and ruminants; the RMS and EFSA consider this suggestion plausible. The formation of additional metabolites to those seen in the livestock studies with thiacloprid is therefore not likely upon animal exposure to M02; however, a prediction of which metabolites precisely will be formed and their quantities in animal commodities is not possible. The RMS considers that M02 is not a relevant residue in animal commodities, assuming a similar transfer factor as for parent. However, EFSA requests further substantiation that livestock exposure to M02 will lead to insignificant residues in ruminant commodities, specifically in kidney and liver. In view of the above described knowledge gaps with regard to animal exposure and residue transfer, EFSA recommends refinement of the livestock burden by generation of higher tier data.

In a hydrolysis study simulating conditions of pasteurisation, boiling/brewing/baking and sterilisation, thiacloprid was demonstrated as stable (97%). Data on M03 are not available, but might also not be necessary.

A residue definition for **animal commodities** can only be provisionally proposed as 'thiacloprid' on the basis of the metabolism studies conducted with parent, however this definition will only be relevant for uses that lead to livestock exposure scenarios where thiacloprid drives the livestock burden which is not the case for the representative uses. Studies in fish were waived based on residue levels and fat solubility of residues in feed items for fish. As the risk assessment definition for oilseed is not finalised, reconsideration of residues in oilseed and subsequently of fish exposure might be necessary as follow-up action.

In the residue trials on maize and oilseed rape, besides analysis for thiacloprid alone, a common moiety method was used to determine total residues oxidised to M03 and expressed as thiacloprid, and residues above the LOQ (0.01 and 0.05 mg/kg, respectively) were not quantified in maize kernels and in rape seed. Significant residues of thiacloprid and of total residues oxidised to M03 and expressed as thiacloprid were found in green parts of the plants, and of total thiacloprid in oilseed rape straw. The number of trials in oilseed rape and maize is sufficient to support the requested uses. However, maize stover was not analysed but is a commodity relevant for livestock exposure and therefore such data are requested (data gap).

Rotational crop residue trials are not available to determine concentrations of metabolites in rotational crops under actual field conditions but the generation of higher tier residue studies is recommended in order to refine consumer and livestock exposure assessments and permit finalisation of the residue definitions as explained earlier in the respective paragraphs (data gap).

In a processing study for oilseed rape, thiacloprid did not concentrate in oil, but there was some concentration of residues in the extracted meal following the drying process and for pomace there was potential concentration.

Stability of residues during sample storage is sufficiently demonstrated across a variety of commodities by the overall data set available; however, the original study report of one of the core studies in this data set should be provided for final validation of the data (data gap).

In a ruminant feeding study, transfer of residues in animal matrices was investigated upon dosing cows with thiacloprid. As for the representative uses, there is no livestock exposure to thiacloprid but to metabolites M02 and M30, the study is not relevant to support the current assessment.

A limited number of residue data in pollen and honey indicated that residues in this commodities will likely be below 0.05 mg/kg; however, the available data may not be sufficient having regard to current (data gap for storage stability in honey) and future standards and requirements of reliable data generation (refer to evaluation table Open point 3.7).

The consumer risk assessment conducted with the EFSA PRIMo rev. 2 and using an LOQ of 0.01 mg/kg for maize (i.e. for residues of thiacloprid alone) and of 0.05 mg/kg for rape seeds (as total thiacloprid, oxidised to 6-CNA, expressed as thiacloprid) indicated that consumer exposure corresponds

to 4% ADI and 3.6% ARfD. The estimates are provisional with regard to the unfinalised assessments for the primary oilseed crop (fate of the thiazolidine moiety), rotational crops (concentration of metabolites under field conditions and fate of the thiazolidine moiety) and the potential transfer of residues in animal commodities. Although with the available data for the representative uses concentrations of thiacloprid < 0.01 mg/kg could be demonstrated in food and feed items, it might be surmised that concentrations of thiacloprid metabolites in food items (rotational crops) and feed items could reach or even exceed this level.

A data gap and issue that could not be finalised for consumer risk assessment has been identified in Section 4 with regard to water treatment processes.

3.2. Maximum residue levels and confirmatory data MRL review

The confirmatory data identified during the review of the existing MRLs according to Article 12 of Regulation (EC) 396/2005 (EFSA, 2014a) and assessed under this review resulted in the following outcome: The requirements for a maize metabolism study and a monitoring method for tea fermented leaves are fulfilled.

4. Environmental fate and behaviour

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, thiacloprid exhibited very low to low persistence, forming the major (> 10% applied radioactivity (AR)) metabolites M02 (max. 87% AR), M29 (max. 33% AR) and M30 (max. 20% AR), which exhibited moderate to high, medium to very high and moderate to medium persistence, respectively. Mineralisation of the methylene group and thiazolidine ring ^{14}C radiolabels to carbon dioxide accounted for 6–41% AR after 100 to 120 days. The formation of unextractable residues (not extracted by methanol, followed by water then soxhlet extract with methanol/water) for these radiolabels accounted for 22–30% AR after 100–120 days. The soil metabolites identified in lysimeter leachate M34 and M46 both exhibited low to moderate persistence, in soil laboratory incubations under aerobic conditions in the dark. In anaerobic soil incubations, thiacloprid exhibited very low persistence forming M02 (max. 85%) which exhibited high persistence. That is, its behaviour was comparable to that which occurred in aerobic incubations. In a laboratory soil, photolysis experiment thiacloprid transformation was faster in the dark control than under illuminated conditions. Thiacloprid exhibited medium to low mobility in soil. M02 and M29 exhibited medium mobility, while M30, M34 and M46 all exhibited very high soil mobility. It was concluded that the adsorption of all these compounds was not pH dependent. In satisfactory field dissipation studies carried out at three sites in Germany, two in the UK, two in France and one in Spain (spray application to the soil surface on bare soil plots or where grass subsequently germinated in late spring or summer) thiacloprid exhibited low to moderate persistence. M02 exhibited moderate to high persistence and M30 exhibited high persistence. Sample analyses were not carried out for metabolite M29 though its investigation was triggered according to the data requirements and the persistence exhibited in aerobic laboratory soil incubations. This is identified as a data gap (see Section 7). The exposure assessment at the EU level has been completed using the available laboratory kinetic end points for metabolite M29. Field study DegT50 values were derived for just the parent thiacloprid following normalisation to FOCUS reference conditions (20°C and pF2 soil moisture) following the EFSA (2014b) DegT50 guidance. These field data end points for parent thiacloprid were combined with lab values to derive thiacloprid modelling end points.

In a lysimeter study of 3 years duration, soil monolith depth 1.25 m located in Monheim Germany with applications being made in the first 2 years to a grass crop at 0.765 kg/ha (ca. 6.9N) the chromatographically resolved components in percolate accounting for > 0.1 μg/L, as annual average concentrations were M30, M34 and M46 at up to 6.92, 0.52 and 0.3 μg/L, respectively.

In laboratory incubations in dark aerobic natural sediment water systems, thiacloprid exhibited moderate persistence, forming the major metabolite M02 (max. 62% AR in water and 37% in sediment) which exhibited medium to high persistence. Metabolite M30 reached levels triggering assessment (max. 9.5% AR in water). The unextractable sediment fraction (not extracted by acetonitrile followed by dichloromethane then soxhlet extract with acetonitrile) was a sink for the methylene group ^{14}C radiolabel, accounting for 17–22% AR at 100 days. Mineralisation of this radiolabel accounted for only 4% AR at 100 days. The rate of decline of thiacloprid in a laboratory sterile aqueous photolysis experiment was slow relative to that occurred in the aerobic sediment water

incubations. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for thiacloprid and the metabolites M02, M29 and M30 using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the Steps 1-2 in FOCUS calculator). For thiacloprid, M02 and M29 appropriate step 3 (FOCUS, 2001) and for the use on oilseed rape for thiacloprid and M29, step 4 calculations were available.[10] These step 4 calculations appropriately followed the FOCUS (2007) guidance, with spray drift mitigation not exceeding 95% spray drift reduction and runoff not being mitigated by more than 90% (i.e. not reducing solute flux in run-off by more than 80% and erosion runoff of mass adsorbed to soil by more than 95%). The SWAN tool (version 4.0.1) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that while run-off mitigation is included in the step 4 calculations available, the FOCUS (2007) report acknowledges that for substances with K_{Foc} < 2,000 mL/g (i.e. thiacloprid and M29), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds. Because groundwater can become surface water, the PEC in groundwater for the lysimeter metabolites M34 and M46 have been used to complete an aquatic risk assessment (see Section 5).

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4[9]. The potential for groundwater exposure from the representative uses by thiacloprid and metabolites M02 and M29 above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios. For the metabolites M30, M34 and M46, the available groundwater exposure assessment indicates that annual average recharge concentrations moving below 1 m depth will be above the limit of 0.1 μg/L for the representative uses in all the relevant groundwater scenarios. These concentrations were predicted to be 0.128–1.696, 0.13–2.16 and 0.277–4.909 μg/L for M30, M34 and M46, respectively. These metabolites have been assessed as relevant (see Section 2). This results in the identification of a critical area of concern (see Sections 9.2 and 9.3).

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. This has led to the identification of a data gap (see Section 7) and results in the consumer risk assessment not being finalised (see Section 9).

The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The following documents were considered in the risk assessment: European Commission (2002a,b), SETAC (2001), EFSA (2009) and EFSA PPR Panel (2013).

Some parts of the risk assessment have been discussed in the Pesticide Peer Review meeting 183 in September, 2018.

The information to support the compliance of the batches used in ecotoxicological studies with the technical specification was considered sufficient.

On the basis of the available data and assessments, a low dietary acute and long-term risk to birds and mammals was concluded for the representative use in oilseed rape in tier 1. As regards the representative use in maize, the tier 1 dietary risk assessments indicated a high acute and long-term risk to birds and mammals. Numerous data were available for refinements (identification of focal species, ecological data, residue behaviour in food items, agronomical parameters). The majority of the data were not deemed suitable for use in quantitative risk assessments, however they were considered in a qualitative manner considering also the level of associated uncertainty. Overall, it was concluded that a low risk for the representative use in maize was not demonstrated for birds and mammals and therefore a high risk remains as identified at tier 1.

Risk assessment for secondary poisoning was not triggered. The risk via consumption of contaminated water was assessed as low. A low risk was concluded for the relevant plant metabolites for the representative use in oilseed rape. However, insufficient data were available for an appropriate risk assessment for the relevant plant metabolites for representative use in maize (data gap).

[10] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

Toxicity data were available for all the relevant aquatic taxa and the active substance. In addition, a mesocosm study for aquatic invertebrates was available. The available information regarding the long-term risk to aquatic invertebrates indicated that Emphemeroptera are amongst the most sensitive taxa. However, no suitable end point could be established (there was a lack of consideration of reproductive effects and potential differences in sensitivity between winter and summer generations). Therefore, as agreed in the experts' meeting,[11] the risk assessment for this group of organisms and as a consequence for the aquatic organisms in general, could not be finalised (data gap and issue that could not be finalised). In addition, it is noted that a low risk for other taxonomic groups for the representative use on oilseed rape could only be concluded with appropriate risk mitigation measures (except for algae where a low risk could be concluded at FOCUS step 1).

Sufficient toxicity data for aquatic organisms were available for the metabolites M02 and M30 and an appropriate end point was available for the metabolite M29 on sediment dwelling organisms representing aquatic invertebrates (the most sensitive group of aquatic organisms for thiacloprid). Considering these data and the available FOCUS step 1–3 predictions, a low risk was concluded for these metabolites with the exception of a drainage scenario for M29 (D1 for the oilseed rape use). FOCUS step 4 calculations did not reduce the Step 3 PEC, therefore a high risk was identified for this FOCUS scenario for the use on oilseed rape. As regards the groundwater metabolites M34 and M46, a low risk to aquatic organisms was concluded considering the toxicity data from their precursor (M30).[12]

Acute toxicity data on honeybees were available for the active substance and the representative formulations. In addition, chronic data on adult honeybees and acute data on larvae were available. As regards the representative use on oilseed rape, the risk assessment was conducted according to the SANCO Guidance on terrestrial ecotoxicology (European Commission, 2002a), i.e. only the acute data for honeybees were taken into consideration. The tier 1 risk assessment based on this data indicated a low risk to honeybees. Some considerations (i.e. semi-quantitative risk assessments) to the other aspects (chronic risk to adults, risk to larvae) were also provided. For these assessments, the available laboratory data, semi-field and field studies, the data on pollen and nectar residues and the available information on residues in green material and residues in flowers were taken into consideration. Based on this, the RMS has considered that a low risk to honeybees can be concluded. However, considering the uncertainties associated to the presented semi-quantitative risk assessments, EFSA concluded that a low risk, other than acute risk, was not demonstrated (data gap leading to an issue that could not be finalised).[13]

As regards the representative use on maize, similar considerations were provided as for the representative use on oilseed rape (similar data and information was available) and the RMS has concluded a low risk to honeybees based on a weight of evidence (WoE) approach. EFSA agreed with the low risk conclusion for acute and chronic risk (effects on mortality of adults) considering the exposure routes via systemic translocation from the soil. However, EFSA considers that a low risk to larvae or a low risk via other routes of exposure (dust drift, risk via consumption of contaminated water) was not demonstrated (data gap leading to an issue that could not be finalised).[13]

Furthermore, it is noted that the available data for bees indicated that some delayed effects or relevant sub-lethal effects at relatively low concentrations cannot be excluded, as well as there were some indications to synergistic effects with other chemical or biological stressors.

A number of plant metabolites were identified to be present or potentially present in pollen and nectar. A low risk to bees could not be demonstrated with the available data and assessments for these metabolites (data gap leading to an issue that could not be finalised).[14]

No data were available on solitary bees, but limited information was available for bumble bees (acute contact test and some information from the literature). This data indicated that bumble bees are not more sensitive to thiacloprid than honeybees (acute contact); however (considering also the available information on residues in pollen and nectar), risk via oral exposure cannot be excluded.

Based on Tier 1 risk assessment, a high in-field and off field risk to non-target arthropods was concluded for the representative use on oilseed rape. A number of additional laboratory studies were available, however a low in-field or off-field risk could not be demonstrated by using these studies. Two appropriate field studies were also available. One of the field studies were considered to be

[11] Refer to experts' consultation 5.3 in the Report of Pesticides Peer Review experts' meeting 183 (EFSA, 2018).
[12] Refer to experts' consultation 5.5 in the Report of Pesticides Peer Review experts' meeting 183 (EFSA, 2018).
[13] Refer to Open point 5.32 of the evaluation table of thiacloprid.
[14] Refer to Open point 5.31 of the evaluation table of thiacloprid.

representative for central European off-field conditions (CEU) and the other one was considered to be representative for southern European off-field situations (SEU). Since no appropriate end point could be derived from the study representative for SEU (significant effects were seen at the lowest tested rate of 0.56 g/ha), a low risk could not be concluded for SEU and therefore a high risk remains as identified at tier 1. However, a suitable end point (NOER of 0.56 g/ha) was agreed for CEU.[15] Considering this end point a low off-field risk to non-target arthropods was concluded for the representative use on oilseed rape provided that a risk mitigation of a 10 m non-spray buffer zone is taken into consideration. It is noted that with this condition the recolonisation of the in-field habitats from off-field areas is possible, whether actually this will happen, was not demonstrated and therefore high in-field risk remains as identified at tier 1.

The exposure of non-target arthropods from the use on maize was considered as low. Considering this and the available data and assessments (including the risk assessments for soil macroorganisms), a low risk to non-target arthropods was concluded for this representative use. However, some concerns were raised during the peer-review regarding the exposure to dust drift (i.e. off-field risk) and the experts recommended that in order to reduce the dust drift, the best available technologies should be considered when thiacloprid is used as seed treatment for maize.[15]

Based on the available laboratory toxicity data, a high risk was concluded for earthworms for the representative uses. However, a field study was available with the representative formulation for the oilseed rape use. On the basis of this study a low risk was concluded for this use. However, a low risk for earthworms was not demonstrated for the representative use in maize (i.e. high risk as identified at tier 1).

Low risk for soil macroorganisms other than earthworms was demonstrated for the representative use on maize, but in lack of toxicity data for soil mites (*Hypoaspis aculeifer*), this was not demonstrated for representative use in oilseed rape (data gap). The risk to soil microorganisms was concluded to be low for both representative uses. Moreover, the risk assessments using the available data for the metabolites M02, M29 and M30, indicated a low risk to soil organisms (earthworms, other soil macroorganisms, soil microorganisms) for the representative uses.

Considering the low exposure, a low risk was concluded for non-target terrestrial plants for the representative use in maize. Also, a low risk was concluded for pre-emergent plants for the representative use in oilseed rape. However, in lack of appropriate data, a low risk was not demonstrated to post-emergent terrestrial non-target plants (data gap).

Based on the available data, a low risk was concluded to organisms involved in sewage treatment processes.

Thiacloprid was identified as an ED for mammals based on scientific information submitted (see section 2). Additionally, a fish full life cycle test was available showing acceleration of sexual maturation. However, since other non-inclusion criteria are already met, EFSA considered that an ED assessment in line with current guidance for the identification of endocrine disruptors in the context of Regulation (EU) No 1107/2009 (ECHA and EFSA, 2018) is not necessary for thiacloprid (see Section 2).

[15] Refer to experts' consultation 5.6 in the Report of Pesticides Peer Review experts' meeting 183 (EFSA, 2018).

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Thiacloprid	Very low to moderate persistence Single first-order DT_{50} 0.33–3.35 days (20°C 40–55% MWHC soil moisture) European field dissipation studies single first-order DT_{50} 6–17 days	High risk to soil organisms for the use on maize
M02	Moderate to high persistence Single first-order DT_{50} 15–167 days (20°C 40–55% MWHC soil moisture) European field dissipation studies Single first-order and biphasic kinetics DT_{50} 24–322 days (DT_{90} 197–1,070 days)	Low risk to soil organisms
M29	Medium to very high persistence Single first-order and biphasic kinetics DT_{50} 83–635 days (DT_{90} 277–> 1,000 days, 20°C 40% MWHC)	Low risk to soil organisms
M30	Moderate to high persistence Single first-order DT_{50} 10–73 days (20°C 40–55% MWHC soil moisture) European field dissipation studies single first-order DT_{50} 122–190 days	Low risk to soil organisms

DT_{50}: period required for 50% dissipation; DT_{90}: period required for 90% dissipation; MWHC: maximum water-holding capacity.

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
Thiacloprid	Medium to low mobility K_{Foc} 393–870 mL/g	No	Yes	Yes
M02	Medium mobility K_{Foc} 223–438 mL/g	No	Assessment not triggered	Yes It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the parent

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[(a)]	Pesticidal activity	Toxicological relevance
M29	Medium mobility K_{Foc} 338–407 mL/g	No	Assessment not triggered	Yes It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the parent
M30	Very high mobility K_{Foc} 15–28 mL/g	Yes 0.128–1.696 µg/L with the exception of just use in winter oilseed rape at the Chateadun scenario where 0.08 µg/L was predicted	Yes	Yes It cannot be excluded that the metabolite shares the carcinogenic properties of the parent
M34	Very high mobility K_{doc} 4–10 mL/g	Yes 0.13–2.16 µg/L	No	Yes It cannot be excluded that the metabolite shares the carcinogenic properties of the parent
M46	Very high mobility K_{Foc} 6–14 mL/g	Yes 0.277–4.909 µg/L	No	Yes It cannot be excluded that the metabolite shares the carcinogenic properties of the parent

K_{Foc}: Freundlich organic carbon adsorption coefficient.
(a): FOCUS scenarios or a relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Thiacloprid	The risk assessment to aquatic organisms could not be finalised
M02	Low risk to aquatic organisms
M29	High risk to aquatic organisms for just the use on winter oilseed rape (two applications) at the FOCUS D1 scenario
M30	Low risk to aquatic organisms
M34 (when groundwater becomes surface water)	Low risk to aquatic organisms
M46 (when groundwater becomes surface water)	Low risk to aquatic organisms

FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use.

Table 4: Air

Compound (name and/or code)	Toxicology
Thiacloprid	Rat LC_{50} inhalation = 1.2 mg/L air/4 h (directed-flow nose-only): Acute Tox. 4, H332 'Harmful if inhaled'

LC_{50}: lethal concentration, 50%.

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- The search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health as reported in the mammalian toxicology section was considered insufficient to conclude whether relevant published literature may have been missed due to the criteria used to assess the relevance of the published literature, such as the requirement of the impurity profile of the test material (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Information on the identity of polymeric co-formulants (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Analytical methods for monitoring of M29, M30, M34 and M46 in surface water and M30, M34 and M46 in groundwater (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- An analytical method for monitoring of M07 in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 2).
- Comparative *in vitro* interspecies metabolism study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Phototoxicity and photogenotoxicity potential of the active substance to be investigated (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; it is acknowledged that there is no validated test guideline available to address these end points; see Section 2).
- The original storage stability study by Allison & Moore (2002), report no. 200120 (United Kingdom, 2018) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Storage stability data in honey to render the available residue trials reliable (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3)
- Additional information that addresses the fate of thiacloprid with regard to the thiazolidine moiety in primary oilseeds/pulses and considerations with regard to metabolites arising from the thiazolidine moiety in rotational crops (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Higher tier rotational crop field studies in order to refine consumer and livestock exposure assessments. It is recommended to investigate metabolites M02 and M30, considering critical soil concentrations, and to additionally include M37 and M34 for confirmatory purposes of current assumptions on their occurrence (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3)
- Residue data in maize stover as relevant maize commodity (relevant for the representative use in maize; submission date proposed by the applicant: unknown; see Section 3)
- Field soil dissipation investigations were not available where metabolite M29 had been included as a target for the analytical method in the studies. Data investigating this are needed according to the data requirements. The exposure assessment at the EU level has been completed using the available laboratory kinetic end points for metabolite M29 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Information to address the effect of water treatment processes on the nature of residues present in surface water, when surface water is abstracted for drinking water was not available. Probably, in the first instance, a consideration of the processes of ozonation and chlorination would appear appropriate. If an argumentation is made that concentrations at the point of abstraction for drinking water purposes will be low, this argumentation should cover

metabolites predicted to be in surface water, as well as the active substance. Should this consideration indicate novel compounds might be expected to be formed from water treatment, the risk to human or animal health through the consumption of drinking water containing them would need to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Sufficient information for an appropriate risk assessment for birds and mammals for the relevant plant metabolites (relevant for the use in maize; submission date proposed by the applicant: unknown; see Section 5).
- Appropriate end point for aquatic invertebrates to be used for the risk assessment to parent thiacloprid (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Appropriate end point for honeybee larvae and appropriate risk assessment for bees (adult and brood), which covers dietary risk, risk from dust drift, risk from consumption of contaminated water and risk from metabolites, e.g. a risk assessment according to EFSA, 2013 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Appropriate toxicity data for soil mites (*Hypoaspis aculeifer*) and thiacloprid (or the representative formulation) (relevant for the use in oilseed rape; submission date proposed by the applicant: unknown; see Section 5).
- Appropriate data for post-emergent terrestrial non-target plants (i.e. vegetative vigour test) (or the representative formulation) (relevant for the use in oilseed rape; submission date proposed by the applicant: unknown; see Section 5)

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

8.1. Particular conditions proposed for the representative uses evaluated

- Control measures and personal protective equipment have been taken into consideration to minimise operator and worker exposure, in particular for operator exposure to seed treatment (Thiacloprid FS 400): seed purification before treatment; use of binders/stickers in the seed treatment slurry; closed transfer systems during mixing/loading; automated mixing of co-applied products; gentle transport of seed; closed treatment line and treatment chamber; automated, closed bagging line; automated, enclosed palletising; cleaning with the use of vacuum equipment not compressed air; adequate dust aspiration system throughout the seed treatment process. Suitable protective coverall (Meeting the requirements of EN 14605 Protective clothing against liquid chemicals – Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections) and chemical resistant gloves to be worn during mixing/loading, cleaning and calibration; suitable protective gloves to be worn when coming into contact with contaminated surfaces or treated seeds and FFP3 RPE to be worn during cleaning operations (see Section 2).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[16] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

[16] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1) The need for further tests and risk assessment to unique human metabolites could not be finalised whilst a comparative *in vitro* interspecies metabolism study was not submitted (see Section 2).
2) The consumer risk assessment with regard to residues in food and feed is not finalised. Although concentrations of thiacloprid < 0.01 mg/kg could be demonstrated in food and feed items, it might be surmised that concentrations of thiacloprid metabolites in some food and feed items could exceed this level (see Section 3).
3) The consumer risk assessment could not be finalised whilst information on the effect of water treatment processes on the nature of residues present in surface water, when surface water is abstracted for drinking water was not available (see Section 4).
4) The risk assessment for birds and mammals from the relevant plant metabolites on maize was not finalised (see Section 5).
5) The risk assessment for aquatic organisms was not finalised (see Section 5).
6) The risk assessment for bees was not finalised (see Section 5).
7) The risk assessment for terrestrial non-target plants was not finalised (see Section 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

8) The approval criteria for thiacloprid according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009 are not met since the harmonised classification of thiacloprid includes toxic for reproduction category 1B (Repro. 1B), unless the exposure of humans to that active substance, under realistic proposed conditions of use is negligible (see Section 2).
9) The available groundwater exposure assessments indicate that for the relevant groundwater metabolites M30, M34 and M46, annual average recharge concentrations moving below 1m depth will be above the parametric drinking water limit of 0.1 μg/L for both the representative uses in all the relevant FOCUS groundwater scenarios (see Sections 2 and 4).

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns

Representative use		Oilseed rape foliar spray	Maize seed treatment
Operator risk	Risk identified		X[(b)]
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised	X[2,3]	X[2,3]
Risk to wild non-target terrestrial vertebrates	Risk identified		X[(d)]
	Assessment not finalised		X[4]
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X	X
	Assessment not finalised	X[6] X[7]	X[6]
Risk to aquatic organisms	Risk identified	1/7 FOCUS scenarios[(c)]	
	Assessment not finalised	X[5]	X[5]
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure to metabolites	Legal parametric value breached	X[9]	X[9]
	Parametric value of 10 μg/L[(a)] breached		
	Assessment not finalised		

Superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).
(b): In one of three treatment plant exposure experiments.
(c): Applies only for winter oilseed rape.
(d): Based on lower tier, low risk was not demonstrated.

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Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CEU	central European off-field conditions
CLP	classification, labelling and packaging
DMS	dimethylsulfate
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
ED	endocrine disruptor
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FS	flowable suspension
GAP	Good Agricultural Practice
HPLC–MS	high-pressure liquid chromatography with tandem mass spectrometry
InChiKey	International Chemical Identifier Key
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC_{50}	lethal concentration, median
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
MoA	mode of action
MRL	maximum residue level
MWHC	maximum water-holding capacity
NOAEL	no observed adverse effect level

NOEL	no observed effect level
NOER	no observed effect rate
OD	oil dispersion
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PPE	personal protective equipment
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe
RAR	Renewal Assessment Report
RMS	rapporteur Member State
SEU	southern European off-field conditions
SMILES	simplified molecular-input line-entry system
STOT-SE	specific target organ toxicity – single exposure
TRR	total radioactive residue
UV	ultraviolet
WHO	World Health Organization
WOE	weight of evidence

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2019.5595

Appendix B – Evaluation of data concerning the necessity of thiacloprid as an insecticide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2019.5595

Appendix C – Data collection set

Validated Excel files submitted by MS (Austria, 2018, Belgium, 2018, Bulgaria, 2018, Denmark, 2018, Finland, 2018, Germany, 2018, Greece, 2018, Hungary, 2018, Latvia, 2018, Lithuania, 2018, Poland, 2018, Romania, 2018, Slovakia, 2018, Spain, Sweden, 2018 and United Kingdom, 2018) and evaluated by EFSA under Article 4(7) of Regulation (EC) 1107/2009.

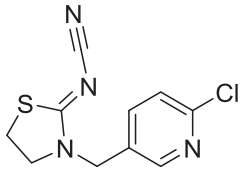
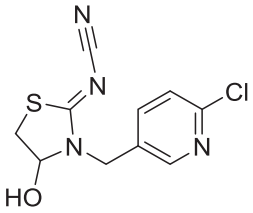
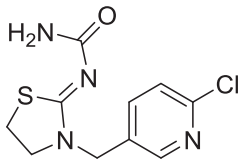
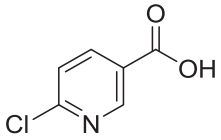
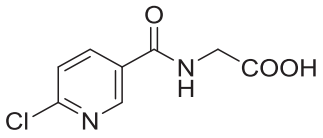
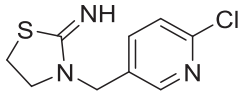
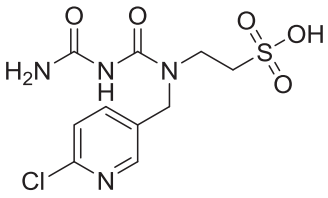
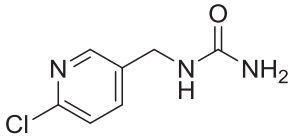
Appendix C can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2019.5595

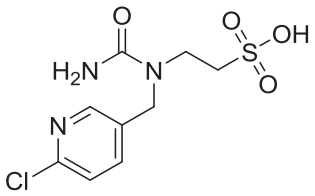
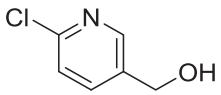
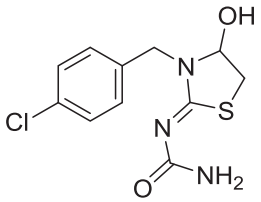
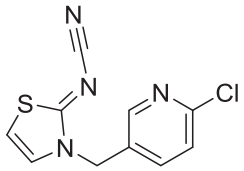
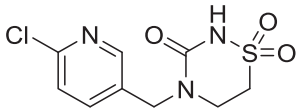
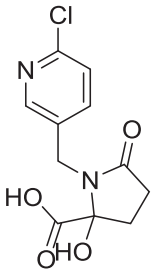
Appendix D – Pest Classification

Information on the taxonomy of the pests considered under the evaluation of the derogation for thiacloprid under Article 4(7) of Regulation (EC) 1107/2009.

Appendix D can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2019.5595

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[b]
Thiacloprid YRC 2894	{(*Z*)-3-[(6-chloro-3-pyridyl)methyl]thiazolidin-2-ylidene} cyanamide N#C/N=C1SCCN\1CC2=CC=C(Cl)N=C2 HOKKPVIRMVDYPB-UVTDQMKNSA-N	
M01 4-hydroxy-YRC 2894	(*Z*)-*N*-(3-((6-chloropyridin-3-yl)methyl)-4-ydroxythiazolidin-2-ylidene)cyanamide ClC1=NC=C(CN2C(O)CS/C2=N\C#N)C=C1 XXFNYZIMZUWOAV-UVTDQMKNSA-N	
M02 thiacloprid-amide Amide-YRC2894	(*Z*)-1-(3-((6-chloropyridin-3-yl)methyl)thiazolidin-2-ylidene) urea O=C(N)/N=C1SCCN\1CC2=CC=C(Cl)N=C2 LEZHOZPJYAQQNU-UVTDQMKNSA-N	
M03 6-chloronicotinic acid IC-0 6-CNA	6-chloronicotinic acid ClC1=NC=C(C(O)=O)C=C1 UAWMVMPAYRWUFX-UHFFFAOYSA-N	
M07	(6-chloronicotinoyl)glycine ClC1=NC=C(C=C1)C(NCC(O)=O)=O VGSLNHSCEKVAIM-UHFFFAOYSA-N	
M29 thiacloprid-des-cyano	3-((6-chloropyridin-3-yl)methyl)thiazolidin-2-imine N=C1SCCN1CC2=CC=C(Cl)N=C2 WJLMZDWUGGHQEH-UHFFFAOYSA-N	
M30 thiacloprid-sulfonic acid YRC2894 sodium Sulfonate	2-(3-carbamoyl-1-((6-chloropyridin-3-yl)methyl)ureido) ethane-1-sulfonic acid ClC1=CC=C(C=N1)CN(C(NC(N)=O)=O)CCS(=O)(O)=O UCZRQNICFJGZAI-UHFFFAOYSA-N	
M31 6-chloropicolyl urea	1-((6-chloropyridin-3-yl)methyl)urea O=C(N)NCC1=CC=C(Cl)N=C1 GDAKHACCQXCCDP-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[b]
M34 thiacloprid-sulfonic acid amide	2-(1-((6-chloropyridin-3-yl)methyl)ureido)ethane-1-sulfonic acid ClC1=CC=C(CN(CCS(=O)(O)=O)C(N)=O)C=N1 NTWIWWZFSUKDGZ-UHFFFAOYSA-N	
M36 6-CPA (free)	(6-chloropyridin-3-yl)methanol OCC1=CN=C(Cl)C=C1 GOXYBEXWMJZLJB-UHFFFAOYSA-N	
M37 4-hydroxy YRC2894 Amide	(*Z*)-1-(3-(4-chlorobenzyl)-4-hydroxythiazolidin-2-ylidene) urea NC(/N=C1SCC(N\1CC2=CC=C(C=C2)Cl)O)=O RSPMUINZMOFWAG-KAMYIIQDSA-N	
M38 YRC 2894 olefin	(*Z*)-*N*-(3-((6-chloropyridin-3-yl)methyl)thiazol-2(3*H*)-ylidene)cyanamide ClC1=CC=C(C=N1)CN2C=CS/C2=N\C#N GSPNWTCHDVQYCA-UVTDQMKNSA-N	
M46 thiacloprid-thiadiazine Z5	4-((6-chloropyridin-3-yl)methyl)-1,2,4-thiadiazinan-3-one 1,1-dioxide O=C(N(CC1=CC=C(Cl)N=C1)CC2)NS2(=O)=O VGRVYZQGUVEBCR-UHFFFAOYSA-N	
M49	1-((6-chloropyridin-3-yl)methyl)-2-hydroxy-5-oxopyrrolidine-2-carboxylic acid OC(C1(CCC(N1CC2=CN=C(Cl)C=C2)=O)O)=O VMMDPMFMLQDEDM-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ChemBioDraw v.13.0.2.3021.