

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/I/ADEL 280 SC

Product name(s): ADEL 280 SC/ PYRIFOS ADE 280 SC

Chemical active substances:

Acetamiprid, 250 g/L

Deltamethrin, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

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Version history

When	What
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December 2021	Updated by Applicant
November 2022	Updated by Applicant
February 2024	Updated by Applicant
April 2024	Updated by Applicant
June 2024	zRMS finalised evaluation
August 2024	zRMS took into account in the assessment the data provided by the Applicant after the evaluation carried out in July 2024
October 2024	zRMS finalised evaluation after commenting period
March 2025	Additional data added by the Applicant
July 2025	Evaluation of additional data by zRMS
September 2025	Update due to change in MRL values for acetamiprid in honey

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zRMS comments:

This report has been completed by the Applicant.

The text highlighted in grey was provided by the zRMS.

The text highlighted in pink was added by zRMS in relation to new data provided by the Applicant in July 2024. Changes made by zRMS after the comment period are marked in dark green.

The evaluation of new data provided by the applicant in March 2025 is marked in red.

Changes made by zRMS after increasing the MRL value for acetamiprid in honey are marked in orange.

New and additional data added in February 2024 was highlighted in green.

New and additional data added in July 2024 was highlighted in blue.

New and additional data added in March 2025 was highlighted in aquamarine.

7 Metabolism and residue data (KCA section 6)

Data matching studies for acetamiprid have been evaluated by RMS – Netherland and later by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/I/ADEL 280 SC (ADEL 280 SC/ PYRIFOS ADE 280 SC) INNVIGO is allowed to refer to EU approved reports

In the following document, data for active substance deltamethrin was described during its inclusion on Annex 1 process in 2009. Were reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer (AgroEvo).

In November 30th, 2009r Decis 2.5 EC product has been authorized in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 10 years from date of first authorization of product containing that active substance (in this case December, 1st 2019).

7.1 Summary and zRMS Conclusion

Acetamiprid

As of the assessment date, the applicable MRLs were included in the Regulation (EU) 2019/88. A new version of the regulation will soon come into force. However, SANTE 11278/2021 does not change the MRL values for sugar beet, wheat and rapeseed.

Please note that in May 2024, EFSA published Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites. EFSA Journal, 22(5), e875. It is recommended:

- To modify the residue definition for risk assessment in **leafy and fruit crops** as follows: ‘sum of acetamiprid and N- desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid’.
- To require additional supervised residue trials analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid (IM-2-1), supporting existing and any new intended uses on **leafy and fruit crops**.
- To derive robust conversion factors (CF) from enforcement to risk assessment. Robust CFs for each plant commodity should be derived based on supervised residue trials compliant with authorised or intended GAPs and analysing simultaneously for acetamiprid and N-desmethyl-acetamiprid (IM-2-1).

A risk for consumer has been identified for 38 MRLs currently in place in the EU Regulation. Consequently, it is recommended to lower the existing MRLs for these commodities. This does not apply to crops under consideration for CHR/I/ADEL 280 SC.

The available monitoring data indicate that metabolite IM-2-1 may be a relevant component of the

residues in some commodities belonging to the fruit and leafy crop groups and, **very unlikely in pulses and oilseeds crops**. No major differences were found between unprocessed and processed commodities.

Pulses/oilseeds:

The overall average for the metabolite IM-2-1 in pulses and oilseeds is below 0.01 mg/kg. Metabolite IM-2-1 is below the LOQ in 903 out of the 914 available samples available on pulses and oilseeds. The 11 samples in which metabolite IM-2-1 was quantified correspond to beans with pods (7), peas with pods (2) and peas without pods (2). Therefore, there are no pulses and oilseeds commodities in the short-listed commodities where metabolite IM-2-1 was quantified in more than 10 samples. The quantified values ranged between 0.001 and 0.012 mg/kg. In all samples, the calculated ratio was below the value of 1, meaning that the concentration of IM-2-1 was always lower than the one of acetamiprid. Overall, it is concluded that **the metabolite IM-2-1 is not a relevant component of the residues in pulses and oilseeds**, based to the available monitoring samples.

Regarding pulses/oilseeds, root crops and cereals, the collected monitoring data do not reveal a significant occurrence of IM-2-1 in commodities belonging to these categories. Therefore, **it is not proposed to modify the residue definition for risk assessment in pulses/oilseeds, root crops and cereals, which therefore remains acetamiprid**. Regarding the residue definition for enforcement, the available data do not indicate a need to modify the existing definition because acetamiprid is still a sufficient marker of the residues in all crop groups.

The existing toxicological reference values (ADI = 0.025 mg/kg bw per day; ARfD = 0.025 mg/kg bw) for acetamiprid were derived in the framework of the EU pesticides peer review (European Commission, 2018). However, in the framework of the present mandate, EFSA derived new toxicological reference values for acetamiprid. The newly derived toxicological reference values are lower than the existing ones: **ADI = 0.005 mg/kg bw per day; ARfD = 0.005 mg/kg bw**.

Furthermore, for honey (0.3 mg/kg), it was concluded that risk for consumers was still unlikely for the new MRLs proposed in SANTE/11278/2021. For these crops, risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.

Metabolism in rotational crops

According to the EFSA Journal 2016;14(11):4610: Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT90) 43 days and 20°C lab DT90 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT50) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

However, the study: Hobbs, G., Inns, L., 2012: 14C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops, Report no. RD-02391 assessed in RAR is still protected.

A new study on the nature of residues in rotational crops was conducted for data matching purposes. Metabolism in succeeding crops was investigated with the IM-1-5. [14C]-IM-1-5 was applied on bare soil, supplied as [pyridyl-2,6-14C] decyano-acetamiprid hydrochloride, at a nominal rate of 0.266 kg/ha. The application rate of the study presented in the RAR (The Netherlands, 2015, 2016) was with the same dose 266 g a.s./ha. The seed used for this study was spring wheat, turnip and spinach. Minor uptake of IM-1-5 was observed for spinach and wheat grain. IM-1-5 residues within these sample types were below the 0.01 mg/kg. Some notable uptake of the test item was observed for wheat forage hay and straw. Residues were also detected in turnips above the 0.01 mg/kg. 24.68 % of the total radioactive residues remained bound to wheat hay and 22.26 % bound to wheat straw. However, uptake into the wheat hay, 22.26 % only represented 0.005 mg/kg. Only limited metabolism of IM-1-5 is observed in the crops and therefore no metabolic pathway is proposed. However, the study used sandy loam soil and not calcareous soil. It should be noted that according to the EFSA Journal 2016;14(11):4610 formation of metabolite IM-1-5 occurred only in the soils stated to be calcareous.

The Applicant did not provide a metabolism study taking into account alkaline soils. However, it should

be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. In addition in Poland only 9% of soils are alkaline. Therefore, **it seems that registration of CHR/I/ADEL 280 SC is possible in Poland with the reservation in the label that the product cannot be used on alkaline soils. However, the final decision should be made by risk managers.**

The Applicant provided additional explanations include comparison that demonstrate equivalence of the mentioned studies. zRMS accepts explanations. In the opinion of zRMS, the restriction previously indicated on the label is not required. However, the study presented by the Applicant should first be assessed in “Data matching studies for acetamiprid” to indicate that the studies are equivalent, so **the final decision rests the risk managers.**

Metabolism in livestock

According to the EFSA Journal 2016;14(11):4610: Metabolism studies on livestock conducted on animals dosed with 14 C-acetamiprid at 10 mg/kg dry matter (DM) over 7 (goat) or 17 (poultry) consecutive days were submitted. Most of the radioactivity was excreted in urine and faeces and only 2% of the administrated radioactivity was recovered in organs, tissues, blood and milk or eggs. Acetamiprid was extensively metabolised and not detected in any animal matrices except in milk. The major component was identified as the N-desmethyl metabolite(IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) where residues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg).The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices. Based on these studies, **the residue definition was proposed as ‘IM-2-1 expressed as acetamiprid’ for monitoring and as ‘the sum of acetamiprid and IM-2-1, expressed as acetamiprid’ for risk assessment.** Conversion factors (CF) of 1.3 and 1.1 were derived for milk and other mammalian products, respectively. CF values were concluded to be unnecessary for poultry products. It is highlighted that RMS expressed its disagreement on the livestock residue definition for risk assessment and proposes to include IM-2-1 compound only.

Animal residue definition for monitoring currently implemented in the EU legislation (Reg. (EU) 2019/88) is sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid.

Stability study

The Applicant should indicate access to the study Netzband, D. J. 2003.

The Applicant provided a stability study for acetamiprid in cereal grain and whole plant. Stability has been demonstrated for spring cereal plant and spring cereal grain to cover up to 157 and 149 days freezer storage, respectively. **The presented stability studies do not cover the storage time of sample collection to analysis shown in the residue studies.**

The Applicant provided additional stability study (No DPL/01/2021) of acetamiprid in cereal grain. The study was evaluated and accepted in dRR Part B7 for CHR/I/ACE 200 SE. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. Stability has been demonstrated for cereal grain to cover up to 200 days so cover the storage time of sample collection to analysis shown in the residue studies.

Magnitude of residues in plants

Wheat

EU GAP, EFSA Journal 2016;14(2):4385:

2 appl., interval 14 days, BBCH 51-79, max appl. rate per treatment 42 g a.s./ha, PHI-28 days, SL formulation

Intended GAP: 1 appl., BBCH 37-75, max appl. rate 40 g a.s./ha, SC formulation

The Applicant provided 5 studies performed for the SE formulation and 4 for the SC formulation. Most of

them (all but two studies for SE formulation) are not covered by stability studies for wheat grain. The storage period ranges from 155 to 192 days for wheat grain, while stability studies were performed for a maximum of 149 days in this matrices. Taking the above into account, the results of the presented studies cannot support the proposed use in wheat.

The proposed uses on wheat and triticale are not accepted.

The Applicant provided additional stability study (No DPL/01/2021) of acetamiprid in cereal grain. Stability of acetamiprid has been demonstrated in cereal grain to cover up to 200 days so cover the storage time of sample collection to analysis shown in the residue studies.

All studies showed no acetamiprid residues above LOQ in cereal grain.

The data submitted show that no exceedance of the MRL will occur.

Residues of acetamiprid in straw (SC formulation): 0.076, 0.086, 0.1, 0.26 mg/kg.

Residues of acetamiprid in straw (SE formulation): < 0.01, 0.047, 0.066, 0.29, 0.52 mg/kg

The use is considered acceptable.

Sugar beet

Intended GAP

1 appl., BBCH 12-19, max appl. rate 40 g a.s./ha, SC formulation

The Applicant provided 4 studies performed for the SE formulation and 4 for the SC formulation. All presented studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no acetamiprid residues above LOD in both leaves and roots.

The data submitted show that no exceedance of the MRL will occur.

The use is considered acceptable.

Rapeseed

GAP assessed at EU level:

EFSA Journal 2011;9(7):2328: formulation SG,

1 appl., BBCH 75-81, max appl. rate 50 g a.s./ha, PHI-28,

Residues of acetamiprid in seeds harvested at the PHI: 3 x <0.01; 0.03; 0.04; 2 x 0.08; 0.1 (STMR 0.035 mg/kg)

EFSA Journal 2016;14(2):4385:

2 app., 1st appl. BBCH 59, 2nd appl. BBCH 80, max appl. rate per treatment 42 g a.s./ha, PHI- n.r., two different formulations were investigated (SL and SG) and the highest residue level from these two formulations was selected for MRL calculation.

Residues of acetamiprid in seeds harvested at the PHI ranging from 26 to 43 days: < 0.01; 2 x 0.02; 0.021; 0.036; 0.05; 0.11; 0.20 (STMR 0.036 mg/kg)

Intended cGAP: formulation SC, 1 appl., BBCH 30-70, max appl. rate 40 g a.s./ha

The Applicant provided 8 studies performed for the SE formulation. All presented studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application.

Residues of acetamiprid in seeds harvested at the PHI 39-45: 2 x <0.012; 0.014; 0.015; 0.045; 0.087; 0.089; 0.093 (STMR 0.03 mg/kg).

The data submitted show that no exceedance of the MRL will occur. However, it should be noted that the Applicant did not provide field studies with SC formulation. Taking into account that the STMR values from the studies presented for the SE formulation are very close to the results from studies assessed at EU level for the SG and SL formulations and that the residue results are much lower (HR 0.093 mg/kg) than the applicable MRL value (0.4 mg/kg, Reg. (EU) 2019/88), the MRL in force should not be expected to be exceeded also for SC formulation. In the opinion of zRMS, authorisation based on the data provided is therefore possible, but the final decision should be made by risk managers. Please indicate PHI equal to 45 days.

Processing studies

According to the EFSA Journal 2016;14(2):4385: The effect of processing on the nature of acetamiprid residues was investigated and the results indicated that acetamiprid is hydrolytically stable under standard hydrolysis conditions (Greece, 2001; EFSA, 2011). Thus, residue definitions proposed for primary crops are also applicable for processed commodities.

Some residue trials on olives and gherkins were performed at exaggerated dose rates (10x and 5x, respectively) to generate samples for processing studies (Greece, 2015b). Olives were processed into canned olives or raw oil; the relevant intermediate products – cake and brine – were also analysed for residues. Gherkins were canned; in two trials, washed gherkins and brine were also analysed for residues. However, no details of the processing conditions were provided. A reduction of residues is observed in all processed edible commodities: canned olives, raw olive oil and canned gherkins.

According to Regulation (EU) 283/2013 processing studies are required if residues in plants to be processed are ≥ 0.1 mg/kg. If the level of residues is < 0.1 mg/kg, processing studies shall be carried out if the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is $\geq 10\%$ of the ADI or if the estimated daily intake is $\geq 10\%$ of the ARfD for any European consumer group diet.

Wheat

No residues above 0.1 mg/kg were found and TMDI is $< 10\%$ of the ADI and IESTI is $< 10\%$ (6%) of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

Oilseed rape

No residues above 0.1 mg/kg (HR = 0.093 mg/kg) were found and TMDI is $< 10\%$ of the ADI and IESTI is $< 10\%$ of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

Sugar beet

No residues above 0.1 mg/kg were found and TMDI is $< 10\%$ (0.2%) of the ADI and IESTI is $< 10\%$ of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

Field rotational crop studies

According to the EFSA Journal 2018;16(5):5262: Field studies in NEU and SEU conducted at ca 300 g/ha on bare soil showed that no residues are expected in rotational crops.

Considering that the conditions of application of the representative uses assessed during the renewal and in the new provided by the Applicant study cover the intended use of acetamiprid in CHR/I/ADEL 280 SC, this conclusion is still relevant in the framework of the present assessment.

Honey

Based on the study provided by the Applicant, it can be concluded that residues in honey would lead to a calculated MRL of 0.2 mg/kg by using the new EU MRL calculator of 2015. One of the results exceeds the currently applicable MRL value, i.e. 0.05 mg/kg.

In accordance with Article 6 of Regulation (EC) No 396/2005, the Nufarm Europe GmbH submitted a request to the competent national authority in Austria to modify the existing maximum residue levels (MRLs) for acetamiprid in honey.

According to the EFSA Journal 2022;20(8):7535: EFSA proposes to amend the existing MRL for honey. Risk Managers are given the options to either set an MRL for honey of 2 mg/kg based on the four residue trials provided with the current application (despite the deviation of not having control samples for two trials) or merge two data sets to derive an MRL of 0.3 mg/kg based on six residue trials performed in accordance with the requirements of the honey guidelines. Risk for consumers unlikely for both MRLs proposed.

Based on EFSA opinion, a draft regulation (SANTE/11278/2021) amending the MRL value for honey is now available.

In line with EFSA Journal, 22(5), e8759 which proposed lowering toxicological reference values (ADI and ARfD): For honey, it was concluded that risk for consumers was still unlikely for the new MRLs (0.3

mg/kg), proposed in SANTE/11278/2021. Risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.

Until the MRL value for acetamiprid in honey is raised, uses on oilseed rape are not supported.

According to the decision of the Ministry of Agriculture and Rural Development in Poland in situation where the Applicant has submitted studies which show that the value of 0.3 mg/kg in honey is not exceeded, a conditional acceptance is possible with an indication of the need for re-verification after the publication of the new MRL value.

According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

Deltamethrin

Stability study

Stability of residues in plants according to EFSA Journal 2015;13(11):4309:

Plant products	Category	Commodity	T (°C)	Stability (months)
	High water content	Lettuce	-20	26
		Cabbage	-20	34
		Tomato	-20	24
	High oil content	Cotton seed	-12	30
	Dry/High starch	Cereals grain	-12	9
Studies cover also the stability of the isomers included in the residue definition. Result from the storage stability study on tomatoes (borderline between highwater and acidic commodity) are extrapolated to the acidic commodities. Sources: Sweden, 1998, 2002; FAO, 2002.				

Data are sufficient to cover the trials supporting intended GAPs of CHR/I/ADEL 280 SC.

Metabolism in crops

The metabolism of deltamethrin in primary crops belonging to the groups of fruits (apples and tomatoes), pulses and oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the MRL review (EFSA, 2015). The metabolism studies after foliar and local treatment showed that the metabolic pathway is similar in all crop groups investigated. Deltamethrin was the main component of residues (up to 77% of the total radioactive residue (TRR)) with alpha-R-isomer and trans-isomer accounting for approximately 30–40% of the TRR.

For the intended uses on oilseed rape, wheat and sugar beet, the metabolic behaviour in primary crops is sufficiently addressed.

Deltamethrin is proposed to be used on wheat, oilseed rape and sugar beet which can be grown in rotation with other crops. A rotational crop metabolism study is available and was assessed in the framework of the MRL review (EFSA Journal 2015;13(11):4309). EFSA concluded that the metabolism in rotational crops was comparable to that in primary crops.

For the intended uses, the metabolic behaviour in rotational crops is sufficiently addressed and no further information is required.

The effect of processing on the nature of deltamethrin has been investigated in the framework of Directive 91/414/EEC (Sweden, 2002) and in the framework of the MRL review (EFSA Journal 2015;13(11):4309). It was concluded that deltamethrin is hydrolytically stable under conditions simulating pasteurisation and brewing, baking and boiling. Under sterilisation conditions, significant degradation of deltamethrin in two main metabolites was observed, which were considered during the peer review as well-known plant metabolites with no toxicological relevance, and therefore, this evidence base was accepted during the MRL review (EFSA Journal 2015;13(11):4309). In the MRL review, it was outlined that in the hydrolysis studies, residues were reported as deltamethrin however it was not clear whether the analytical method used analysed for the sum of all isomers.

Residue definition:

For enforcement: deltamethrin (cis-deltamethrin), Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342;

For risk assessment: sum of deltamethrin and its alpha-R isomer and trans-isomer (tentative), EFSA

Journal

2015;13(11):4309

Metabolism in livestock

According to the EFSA Journal 2015;13(11):4309: Metabolism of deltamethrin in ruminants and poultry was investigated in the framework of Directive 91/414/EEC (Sweden, 1998, 2002).

Cows were dosed for three consecutive days with 10 mg/kg body weight (bw) per day (labelled on both the benzyl- and dimethyl-rings, one cow for each label). Deltamethrin was the major compound in all tissues accounting for up to 90% of the TRR in fat. Metabolites Br2CA and PB acid were present at the same level as parent in liver and kidney (23 and 33% of the TRR, respectively).

Hens were dosed for three consecutive days with 5 mg/kg bw per day (also labelled on both rings). In poultry tissues and eggs, deltamethrin was the main compound found (19-65% of the TRR), except in kidney where, apart for deltamethrin (25-28% TRR), metabolites c-Br2CA and c/t-COOH-c-Br2CA (together 22% TRR), and c-CH2OH-c-Br2CA and t-COOH-c-CH2OH-c-Br2CA-lactone (together 15-22% TRR) were also identified.

As metabolic pathways are expected to be similar in ruminants and rodents, the results of the cow metabolism study could be extrapolated to pigs.

Residue definition:

For enforcement: deltamethrin (cis-deltamethrin), Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342;

For risk assessment: sum of deltamethrin and its alpha-R isomer and trans-isomer, EFSA Journal 2015;13(11):4309

Magnitude of residues in plants

Wheat

EU GAP, EFSA Journal 2016;14(2):4385:

3 appl., interval 14 days, BBCH n.a., max appl. rate per treatment 7.5 g a.s./ha, PHI-30 days, EC formulation

Intended GAP: 1 appl., BBCH 37-75, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 4 adequate independent studies performed for the SC formulation. All of them are covered by stability studies for wheat grain. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no deltamethrin residues above LOQ in grain. Straw residue results were found in the range 0.1 mg/kg – 0.46 mg/kg (STMR – 0.155 mg/kg).

The data submitted show that no exceedance of the MRL (1 mg/kg, according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

The proposed uses on wheat and triticale are accepted.

Oilseed rape

EU GAP, EFSA Journal 2015;13(11):4309:

4 appl., interval 14 days, BBCH n.a., max appl. rate per treatment 6.25 g a.s./ha, PHI-45 days, EC formulation

Intended cGAP: 1 appl., BBCH 30-70, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 4 adequate independent studies performed for the SC formulation. All of them are covered by stability studies for wheat grain. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no deltamethrin residues above LOQ in seeds.

The data submitted show that no exceedance of the MRL (0.2 mg/kg according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

The proposed uses of deltamethrin on oilseed rape are accepted.

Sugar beets

EU GAP, EFSA Journal 2015;13(11):4309:

3 appl., BBCH n.a., max appl. rate per treatment 10 g a.s./ha, PHI-3 days, EC formulation

Intended cGAP: 1 appl., BBCH 12-19, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 5 adequate independent studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application.

All studies showed no deltamethrin residues above LOD in roots. One sample of leaves with tops contained deltamethrin at a level of 0.01 mg/kg. No residues above LOD were found in the remaining samples of leaves.

The data submitted show that no exceedance of the MRL (0.02 mg/kg according to Reg. (EU) 2018/832 and 0.01 mg/kg for sugar beet roots in not yet applicable Reg. (EU) 2024/1342) will occur.

The proposed use of deltamethrin on sugar beets is accepted.

Honey

Sugar beet, wheat and triticale have no melliferous capacity therefore magnitude of residues in honey are not necessary. For oilseed rape application new magnitude of residues in honey were provided.

The Applicant provided 4 adequate studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage.

All studies showed no deltamethrin residues above LOD in honey.

Samples were analysed 15 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.

The data submitted show that no exceedance of the MRL (0.05 mg/kg for honey according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

Processing studies

According to the EFSA Journal 2015;13(11):4309: Studies investigating the magnitude of residues in processed commodities of apples, tomatoes, pulses, sunflower seeds, rape seeds, cotton seed, olive, barley, maize, rice (Sweden, 1998, 2002), potatoes (EFSA, 2010) and strawberries (Italy, 2015) were reported. In these studies, residues were always reported as 'deltamethrin' and it is not clear if an analytical method covering all the isomers has been used. Consequently, no robust processing factors for enforcement and risk assessment could be derived. The processing factors should therefore be considered as indicative only.

Residues in succeeding crops

According to the EFSA Journal 2015;13(11):4309: The results of the confined rotational crop study is confirmed by a field rotational crop study analysing residues in spinach, carrots and radishes planted in soil treated once at 0.12 kg a.s./ha. Considering that deltamethrin was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the GAPs assessed in the present review.

Studies evaluated at EU level represent a much worse scenario, the dose proposed in the intended GAP is significantly lower. Residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the intended GAPs.

The proposed uses of deltamethrin and acetamiprid in the formulation CHR/I/ADEL 280 SC do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/I/ADEL 280 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for winter oilseed rape, winter wheat and sugar beets. A list of all intended uses within the zone is given in Part B, Section 0.

The critical GAP was selected from the worst case use on winter oilseed rape, winter wheat, winter triticale and sugar beets of plant protection product CHR/I/ADEL 280 SC and highest maximum rate of 0.04 kg/ha of Acetamiprid and 0.0048 kg/ha of deltamethrin.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.4 mg/kg for Acetamiprid and 0.2 mg/kg for Deltamethrin in winter oilseed rape, 0.1 mg/kg for Acetamiprid and 1mg/kg for Deltamethrin in Winter wheat, 0.01 mg/kg for Acetamiprid and 0.02 mg/kg for Deltamethrin in sugar beets as laid down in Regulation (EU) 2019/88 and Regulation (EU) 2018/832 is not expected.

The chronic and the short-term intakes of acetamiprid and deltamethrin residues are unlikely to present a public health concern.

~~As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).~~

The product cannot be used on alkaline soils - the final decision should be made by risk managers

According to available data, no specific mitigation measures should apply.

According to the decision of the Ministry of Agriculture and Rural Development in Poland in situation where the Applicant has submitted studies which show that the value of 0.3 mg/kg in honey is not exceeded, a conditional acceptance is possible with an indication of the need for re-verification after the publication of the new MRL value.

According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

Data gaps

Noticed data gaps are: None

Acetamiprid:

~~The Applicant should indicate access to the study Netzband, D. J. 2003. The presented stability studies for acetamiprid in cereals grains do not cover the storage time of sample collection to analysis shown in the residue studies.~~

~~The Applicant did not provide a metabolism study taking into account alkaline soils. However, it should be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. In addition in Poland only 9% of soils are alkaline. Therefore, it seems that registration of CHR/I/ADEL 280 SC is possible in Poland with the reservation in the label that the product cannot be used on alkaline soils. However, the final decision should be made by risk managers.~~

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/sy nergist per ha (d)	ZRM's Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. (e)	Membe r state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/sy nergist per ha (f)	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Wate r L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter Oilseed rape (BRSNW) (0401060)	F	<i>Aphids:</i> <i>Brevicoryne</i> <i>brassicae</i> , <i>Myzus</i> <i>persicae</i> , <i>Athalia/Athalia</i> <i>rosae</i>	Spray, medium sprayer	Autumn BBCH 10- 21	a)1 b)1	n/a	a) 0.16 L/ha b) 0.16 L/ha	a) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D) b) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D)	200- 300	n/a 45		Exceeding the applicable MRL for acetamiprid in honey Until the MRL value for acetamiprid in honey is raised, uses on OSR are not supported. According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.
2	PL	Winter Oilseed rape (BRSNW) (0401060)	F	<i>Ceutorhynchus</i> <i>quadridens</i> , syn. <i>C. pallidactylus</i> , <i>Ceutorhynchus</i> <i>napi</i> , <i>Brassicogethes</i> <i>aeneus</i> syn. <i>Meligethes</i> <i>aeneus</i> ,	Spray, medium sprayer	Spring BBCH 30- 70	a)1 b)1	n/a	a) 0.16 L/ha b) 0.16 L/ha	a) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D) b) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D)	200- 300	n/a 45		Exceeding the applicable MRL for acetamiprid in honey. Until the MRL value for acetamiprid in honey is raised, uses on OSR are not supported. According to the Reg. (EU) 2025/1212

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:	ZRM's Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				<i>Ceutorhynchus assimilis</i> , <i>Dasineura brassicae</i>										(applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/sy nergist per ha (6)	ZRM's Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water r L/ha min / max			
3	PL	Winter wheat (TRZAW) (0500090)	F	<i>Sitobion avenae</i> , <i>Thrips</i> sp.	Spray, medium sprayer	Spring BBCH 37- 75	a)1 b)1	n/a	a) 0.16 L/ha b) 0.16 L/ha	a) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D) b) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D)	200- 300	n/a 35		
4	PL	Winter triticale (TTLWI) (0500090)	F	<i>Sitobion avenae</i> , <i>Thrips</i> sp.	Spray, medium sprayer	Spring BBCH 37- 75	a)1 b)1	n/a	a) 0.16 L/ha b) 0.16 L/ha	a) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D) b) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D)	200- 300	n/a 35		
5	PL	Sugar beet (BEAVA) (900010)	F	<i>Aphis</i> sp.: <i>Aphis fabae</i> , <i>Pegomya hyoscyami</i>	Spray, medium sprayer	Spring BBCH 12- 19	a)1 b)1	n/a	a) 0.16 L/ha b) 0.16 L/ha	a) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D) b) (0.04 kg a.s/ha A+0.0048 kg a.s/ha D)	200- 300	n/a		

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/sy nergist per ha (f)	ZRM's Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water r L/ha min / max			
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
7														
8														
Minor uses according to Article 51 (zonal uses)														
9														
10														
Minor uses according to Article 51 (interzonal uses)														
11														
12														

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation CHR/I/ADEL 280 SC is composed of Acetamiprid and Deltamethrin.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Acetamiprid and deltamethrin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Acetamiprid - Parent compound (for uses other than fruits and leafy vegetables)					
ADI	EFSA Journal 2016;14(11):4610 EFSA SANTE/10502/2017 Rev 8 24 September 2024	2016 2024	0.025 mg/kg bw/day 0.005	2 year rat	100
ARfD	EFSA Journal 2016;14(11):4610 EFSA SANTE/10502/2017 Rev 8 24 September 2024	2016 2024	0.025 mg/kg bw 0.005	2 year rat	100
Deltamethrin - Parent compound					
ADI	Deltamethrin, DAR, List of endpoints	2002	0.01 mg/kg bw/d	1 year dog 90 days dog	100
ARfD	Deltamethrin, DAR, List of endpoints	2002	0.01 mg/kg bw/d (As the ADI)	-	100

zRMS comments:

According to the EFSA Journal. 2024;22:e8759: the EFSA WG proposed to lower the acceptable daily intake (ADI) and acute reference dose (ARfD) from 0.025 to 0.005 mg/kg body weight (per day). The new reduced values were also taken into account in the assessment.

7.1.2.1 Summary for acetamiprid

Table 7.1-3: Summary for acetamiprid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter oilseed rape	Yes	Yes (8 for SE instead SC formulation)	Yes	Yes	Yes	Yes No	Yes No
2	Winter wheat	Yes	Yes (5 for SE and 4 for SC	Yes	Yes	Yes		Yes No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
			formulation)					
4	Sugar beets	Yes	Yes (4 for SE and 4 for SC formulation)	Yes	Yes	Yes		Yes No
Not applicable	Honey	Not applicable	Yes (4)	Not applicable	Yes	No Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

Conclusions

Four field studies (Northern France, Poland) were carried on determination of Acetamiprid residues in winter oilseed rape, one plot was treated once with APIS 200 SE at the application rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 45 days before harvest. One plot remained untreated. Samplings were performed at 0, 15, 29, 34 days after the application (DAA) and 45 DAA at BBCH 89 (at maturity of the grain). Residue levels were in range from 0.003 – 0.093 mg/kg, therefore residue levels for all trials are below MRL.

Three field studies (Poland, Germany, Hungary) were carried on determination of acetamiprid residues in winter wheat, the target dose was 40 g a.s. /ha of acetamiprid, foliar applications were performed in BBCH 75 (first application) and BBCH 77 (second application). Samples were collected at commercial harvest. Residue levels were in range from 0.003 – 0.047 mg/kg, therefore residue levels for all trials are below MRL.

Two field studies were carried (Poland) on determination of acetamiprid residues in sugar beet, the target dose was 40 g a.s. /ha of acetamiprid. Application was performed in BBCH 19 (foliar). Specimens for analyses were collected 14 days before harvest and at commercial harvest (BBCH 49) Residue levels are below 0.003 mg/kg, therefore residue levels for all trials below MRL.

4 additional residue studies in sugar beet and winter cereals was performed on formulation ADEL 280 SC to prove that formulation SC will generate residues on similar levels to formulation SE. Data on formulations SC can be classified as bridging studies. Considering provided evidence there is no need to present any further data for oilseed winter rape, in applicant's opinion.

zRMS comments:

zRMS does not agree with the presented by the Applicant opinion. According to the SANTE/2019/12752 Rev01: Residue trials that are performed with a formulation type that is not equivalent to the formulation type specified in the GAP under assessment are not acceptable; a complete data set performed with the formulation type defined in the GAP is required, unless comparable residue behaviour can be demonstrated with bridging studies. However, experience shows that emulsifiable concentrates (EC), wettable powders (WP), dispersible granules (WG), and suspension concentrates (SC) formulations usually produce comparable residues (especially if the last application is more than seven days prior to harvest) and well-justified and documented departures from the above could be considered. More detailed information can be found in MacLachlan and Hamilton (2010) and in the OECD Guidance Document on crop field trials.

Bridging studies should be generated for at least three major crop groups (one crop per group), e.g. a fruit, a leafy crop, a root crop, a cereal/grass crop, pulses and oilseeds, etc. It has proved sufficient to carry out four comparative trials on each crop selected. Trials should preferably be carried out on crops that would

be expected to show high levels of residues.

Acetamiprid is stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites according to EFSA Journal 2016;14(11):4610.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here (Palau I., 2021, ACI19-002). It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, according to live stock feeding studies from EFSA Journal 2016;14(11):4610 , no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Reg. (EU) 2025/158 (not yet applicable) was published in which new MRL values are presented for Acetamiprid. In the context of this particular submission only MRL in some animal matrices were changed. In addition new MRL that influence this section was published by EFSA in *EFSA Journal*, 2025;23:e9300, in which MRL of 1.0 mg/kg was proposed for honey.

In accordance to national polish regulation: *Ustalenia dotyczące sporządzania oceny lub uwag w zakresie środków ochrony roślin przez podmioty upoważnione, Pozostałości (aktualizacja 17.12.2024)*.

W przypadku gdy z przedłożonych badań wynikać będzie, że poziomy pozostałości w miodzie przekraczają wartość LOQ (tj. default MRL dla miodu - 0,05mg/kg), możliwa jest warunkowa rejestracja do czasu wyznaczenia nowej wartości NDP, jeśli projekt rozporządzenia podnoszący wartość NDP jest już opublikowany w bazie Komisji Europejskiej.

According to the decision of the Ministry of Agriculture and Rural Development in Poland in situation where the Applicant has submitted studies which show that the value of 0.3 mg/kg in honey is not exceeded, a conditional acceptance is possible with an indication of the need for re-verification after the publication of the new MRL value.

According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in honey has been raised to 0.3 mg/kg.

7.1.2.2 Summary for Deltamethrin

Table 7.1-4: Summary for Deltamethrin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter oilseed rape	Yes	Yes (5)	Yes	Yes	Yes	Yes No	Yes No
2	Winter wheat	Yes	Yes (4)	Yes	Yes	Yes		Yes No
4	Sugar beets	Yes	Yes (5)	Yes	Yes	Yes		Yes No
Not applicable	Honey	Not applicable	Yes (4)	Not applicable	Yes	Yes		No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

Four field studies (France, Germany, Hungary, United Kingdom) were carried on determination of Deltamethrin residues in winter oilseed rape. In each trial one plot was treated once with DELCAPS at the application rate of 0.1 L/ha (5 g deltamethrin/ha). The application was made at BBCH 59, 90 (± 5) days before harvest. One plot remained untreated. In two trials 4 samplings were performed between BBCH 81 and 89, the last sampling being made at 90-95 days after application (DAA). In two trials 5 samplings were performed between BBCH 81 and 89, the last sampling being made at 86-93 DAA. Residue levels were below 0.003 mg/kg, therefore residue levels for all trials are below MRL.

Four field studies (Poland, Czech Republic, Hungary, Netherlands) were carried on determination of Deltamethrin residues in winter wheat. The samplings were performed between BBCH 83 and 97. Residue levels were in range from 0.003 – 0.0046 mg/kg, therefore residue levels for all trials are below MRL.

Four field studies (Poland, Czech Republic, Hungary, Netherlands) were carried on determination of Deltamethrin residues in spring barley. The samplings were performed between BBCH 83 and 97. Residue levels were in range from 0.003 – 0.016 mg/kg, therefore residue levels for all trials are below MRL.

According to EU regulation 283/2013 studies for substances with a water solubility < 0.01 mg/L are not required. Solubility of Deltamethrin in water is 0.0002 mg/l according to deltamethrin DAR final list of endpoints.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here (Krebs, Eickhoff, and Raquet, 1986). It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, according to live stock feeding studies from EFSA Journal 2015;13(11):4309, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

7.1.2.3 Summary for CHR/I/ADEL 280 SC

Table 7.1-5: Information on CHR/I/ADEL 280 SC (KCA 6.8)

Crop	PHI for CHR/I/ADEL 280 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for CHR/I/ADEL 280 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Acetamiprid	Deltamethrin		
Winter wheat	24-60 n/a	24-37	27-60-35	35	PHI 35 is supported by data
Winter oilseed rape	27-95 n/a	27-41 45	86-95	45	PHI 45 is supported by data
Spring barley	27-31 n/a	NR	27-31	-	Barley is not indicated in the proposed GAP
Sugar beets	66-96 n/a	66-96	NR	-	-

NR: not relevant

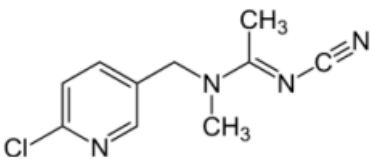
* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

7.2 Acetamiprid

General data on acetamiprid are summarized in the table below (last updated 2017/12/13)

Table 7.2-1: General information on acetamiprid

Active substance (ISO Common Name)	Acetamiprid
IUPAC	(E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine
Chemical structure	
Molecular formula	C ₁₀ H ₁₁ ClN ₄
Molar mass	222.68
Chemical group	Neonicotinoids, IRAC group 4A
Mode of action (if available)	single site mode of action at the nicotinic acetylcholine receptor
Systemic	Yes
Company	Nisso Chemical Europe GmbH
Rapporteur Member State (RMS)	Netherland
Approval status	Approved Date of 24/01/2018 and reference to decision Reg. (EU) 2018/113
Restriction	Reg. (EU) 2018/113 the risk to aquatic organisms, bees and other non-target arthropods, — the risk to birds and mammals, — the risk to consumers, — the risk to operators. Conditions of use shall include risk mitigation measures, where appropriate.
Review Report	SANCO/10502/2017 – rev. 4 13/12/2017
Current MRL regulation	Regulation (EC) No 2019/88 Reg. (EU) 2025/158 - Applicable from 19/08/2025 Reg. (EU) 2025/1212 – Applicable from 20/08/2025
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	EFSA Journal 2016;14(11):4610
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2011;9(7):2328
Current MRL applications on intended uses	N/A – MRL already set

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

New stability of residues data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Apple	High water content	18 12 months	Goller G. 1999, Stability Study of NI-25 (Acetamiprid) in apple and tomato samples after storage in freezer at or below -18°C - Fortification experiments with active ingredient The Netherlands, 2015 Greece, 2001, 2002 Report No RPA/NI-25/97051 EFSA, 2016a
Tomato	High water content	18 12 months	
Fodder pea	High water protein content	12 months	Jean-Baptiste C. 2009 Frozen Storage Stability of Residues of Acetamiprid in Fodder Pea. The Netherlands, 2015, 2016 Report No A7125 EFSA, 2016a
Potato	High starch content	8 months	Netzband, D. J. 2003 Stability study of Acetamiprid in potatoes during frozen storage, USA, 2002 in freezer at or below -18°C The Netherlands, 2015, 2016 Report No RD-00243 EFSA, 2016a Covered by data protection
Oilseed rape Cotton seed, cotton oil, orange oil	High oil content	12 months	EFSA Journal 2016;14(11):4610 The Netherlands, 2015, 2016 Gieseke L.D., 1999 Report No 10201 EFSA, 2016a
New Data			
Turnip	High starch content	156 days	G. Turnbull, 2021. Completion of Analysis of Samples Generated in Study Number ACI19-002
Spring cereal, plant	High water content	157 days	Turnbull, G., 2021, FR/000938-10
Spring cereal, grain	High starch content	149 days	Turnbull, G., 2021, FR/000938-10
Honey	-	37 days	Faessel, V., 2022, C1310

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Wheat, grain	High starch content	200 days	Niewelt, S., 2021, DPL/01/2021

New presented storage stability study in wheat grains (Niewelt, S., 2021, DPL/01/2021) was already evaluated and accepted in the dossier of CHR/I/ACE 200 SE.

Conclusion on stability of residues during storage

~~The storage stability evaluated during Annex I inclusion and renewals covers plant matrices for use CHR/I/ACE according to the label.~~

zRMS comments:

The Applicant should indicate access to the study Netzband, D. J. 2003.

The Applicant provided a stability study for acetamiprid in cereal grain and whole plant. Stability has been demonstrated for spring cereal plant and spring cereal grain to cover up to 157 and 149 days freezer storage, respectively. The presented stability studies do not cover the storage time of sample collection to analysis shown in the residue studies.

The Applicant also provided a stability study of acetamiprid in honey. Results shows that residues are stable over the period of 37 days.

The Applicant provided additional stability study (No DPL/01/2021) of acetamiprid in cereal grain. Stability of acetamiprid has been demonstrated in cereal grain to cover up to 200 days so cover the storage time of sample collection to analysis shown in the residue studies.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

The time between extraction and analysis was always less than 24 hours.

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Not relevant

zRMS comments:

The stability of the analytes through the analytical procedures is adequately demonstrated by the procedural recoveries.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Eggplant	Pyridine-2,6- ¹⁴ C	dotting to the leaf surface, G	9.5	1	7, 14		Saito, H. 1997(3) NI-25 [Pyridine-2,6- ¹⁴ C] - Nature of the Residue in Eggplants EFSA 2016
	Apple	Pyridine-2,6- ¹⁴ C	dotting to the leaf surface,G	208	1	0, 7, 14, 28, 90		Saito, H. 1997(1) NI-25 [Pyridine-2,6- ¹⁴ C] - Nature of the Residue in Apples EFSA 2016
				104		0, 14, 28, 62		
	Leafy vegetables	Cabbage	Pyridine-2,6- ¹⁴ C	Foliar treatment, G	302	1	0, 14, 28, 63	
Soil application, G				5940	7, 14 and 28			
Cyano- ¹⁴ C			Foliar treatment, G	299	0, 7, 14, 28, 63		Kawai,T.; 1995; Metabolism of 14C-Acetamiprid (CN label) in Cabbages EFSA 2016	
Root and tuber vegetables		Carrot	Pyridine-2,6- ¹⁴ C	Foliar treatment, F	100	2	14	
Pulses and oilseeds	Cotton	Pyridine-2,6- ¹⁴ C	Foliar treatment, F	4 x 127	4	14 and 28		Miller N. 1999 Foliarly

								applied ¹⁴ C-acetamiprid: Metabolic fate and distribution in cotton (Gossypium hirsutum). EFSA 2016
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Summary of plant metabolism studies reported in the EU

Acetamiprid main component of residues (almost 50 to 99 % TRR), except in cabbage head and cotton seeds after foliar application where metabolite IC-0 (6- chloronicotinic acid) was detected as major (ca. 46 and 24 % TRR respectively). IC-0 was also present in carrot root at 26% TRR but in this case parent was the major residue.

Conclusion on metabolism in primary crops

The metabolism in primary crops presented in Acetamiprid, RAR, annex B, B.7 Residue (unprotected study), covers use of CHR/I/ADEL 280 SC on winter oilseed rape, winter wheat and sugar beets. No new studies are necessary.

zRMS comments:

No new studies were conducted since the metabolism of acetamiprid was investigated in the studies presented in the RAR (The Netherlands, 2015). Since acetamiprid was identified by far, as the major component of the residues in almost all plant matrices and since the toxicity of the IC-0 metabolite was concluded to be covered by the toxicity of the parent acetamiprid, the plant residue definitions for monitoring and risk assessment were limited to acetamiprid. However, in May 2024, EFSA published a position paper (EFSA Journal, 22(5), e8759) in which it indicated that: The available studies investigating the metabolism of acetamiprid in plants gave an indication that the metabolite IM-2-1 is formed at relatively low levels in edible parts of fruit crops and leafy crops (between 2% and 8% of the TRR; up to 0.3 mg/kg in fruits; up to 1.25 mg/kg in leafy). In inedible leafy matrices, however, this metabolite occurs at higher proportions related to the parent compound, IM-2-1 representing up to 32% of the parent compound (16% of the TRR) in apple leaf at longer preharvest intervals. The monitoring data on the metabolite IM-2-1 confirmed its occurrence in several commodities belonging to the groups of leafy and fruit commodities. In these crop groups, the median proportion of metabolite IM-2-1 compared to the parent compound was found to be significant in fruit and leafy crops (median ratio IM-2-1/acetamiprid accounting for 21%–44%, respectively). It was therefore proposed to include metabolite IM-2-1 in the residue definition of risk assessment for leafy and fruit crops, which is currently limited to the parent acetamiprid. A revised residue definition for risk assessment was proposed for leafy and fruit crops as sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid. **Regarding pulses/oilseeds, root crops and cereals, the new data received under ToR 2a did not indicate a need to modify the existing residue definition for risk assessment, which therefore remains as parent acetamiprid. Regarding the residue definition for enforcement, the available data do not indicate a need to modify the existing definition because acetamiprid is still a sufficient marker of the residues in all crop groups.**

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

New nature of residue in rotational crops performed in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest (BBCH)	Remarks	
New data								
Leafy vegetables	Spinach	[¹⁴ C]-IM-1-5 ([pyridyl-2,6- ¹⁴ C]	Spray, G	266	0	49		Rooney P., 2019, [¹⁴ C]-IM-1-5 Metabolism in Rotational Crops FR/000939
Root and tuber vegetables	Turnip	[¹⁴ C]-IM-1-5 ([pyridyl-2,6- ¹⁴ C]	Spray, G	266	0	49		
Cereals	Wheat	[¹⁴ C]-IM-1-5 ([pyridyl-2,6- ¹⁴ C]	Spray, G	266	0	30, 69, 89		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The only [¹⁴C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue ($\geq 76.8\%$ TRR). No other metabolites or unidentified residues were observed in any crop commodity. In all RACs the PES fraction was less than 8.3% TRR. Thereby, the residue had been sufficiently described and acetamiprid metabolite IM-1-5 is the only relevant residue for risk assessment in rotational crops sown 0 days after treatment of the soil.

The metabolism study in rotational crop (Rooney, P., 2019) was not evaluated in the applicant's finalised data matching table, but the study was designed to be equivalent to study presented by notifier in RAR (Hoobs, G., Inns, L., 2012). For illustrative purpose applicant decided to include comparison that demonstrate equivalence of the mentioned studies:

Aspect of the study	Hobbs, G., Inns, L., 2012, RD-02391	Rooney, P., 2019, FR/000939	Comment
Guideline	OECD 502	OECD 502	Both studies were designed based on the same guideline.
Analytical standard	[Pyridyl- ¹⁴ C]-IM-1-5	[Pyridyl- ¹⁴ C]-IM-1-5	The same analytical standard was applied.
Application dose	Metabolite IM-1-5 was applied on bare soil with rate of 266 g/ha.	Metabolite IM-1-5 was applied on bare soil with rate of 266 g/ha.	In both studies the same amount of IM-1-5 was applied on bare soil.
Rotational crops	Wheat, spinach, turnip were sown just after application of the metabolite IM-1-5.	Wheat, spinach, turnip were sown just after application of the metabolite IM-1-5.	The same crops were sown just after application of the metabolite.

Samplings	Samplings where gathered: - in BBCH 49 for spinach and turnip - in BBCH 30 in seedlings and in BBCH 89 for seeds and straw of wheat	Samplings where gathered: - in BBCH 41-43 and BBCH 49 for spinach and turnip, - in BBCH 22-32 for seedling, in BBCH 55-65 in straw and in BBCH 89 for wheat seeds	In both studies similar sampling points were chosen.
Soil on which metabolite was applied	There is no information on EU level, but as confirmed the study was conducted in accordance to OECD 502. The guideline require to perform the study on sandy loam soil.	Study was performed on sandy loam soil as requested by OECD 502.	It should be assumed that both tests were performed on the same type of soil. Otherwise the study presented by notifier would not be accepted on EU level.
Extraction method	Samples were extracted by mixture of water and acetonitrile (1:1).	Samples were extracted by mixture of water and acetonitrile (1:1).	The same extraction method was applied.
Conclusion based on results	Metabolite IM-1-5 is the only relevant analyte in rotational crops with > 10% TRR.	Metabolite IM-1-5 is the only relevant analyte in rotational crops with > 10% TRR.	Convergent conclusion.

As proven study presented by applicant (Rooney, P., 2019, FR/000939) can be considered as equivalent to study presented on EU level by notifier of the active substance (Hobbs, G., Inns, L., 2012, RD-02391). Based on that fact in applicant's opinion product can be applied on all soil despite its pH.

Conclusion on metabolism in rotational crops

The metabolism in rotational crops presented in Acetamiprid, RAR, annex B, B.7 Residue (unprotected study), covers use of CHR/I/ADEL 280 SC on winter oilseed rape, winter wheat and sugar beets. No new studies are necessary

zRMS comments:

According to the EFSA Journal 2016;14(11):4610: Having regard to the low persistence of acetamiprid in soil (highest field period required for 90% dissipation (DT₉₀) 43 days and 20°C lab DT₉₀ 54 days), confined rotational crop studies were not conducted with the active substance and the metabolism in rotational crops was investigated using the more persistent soil metabolite IM-1-5 (period required for 50% dissipation (DT₅₀) 319–663 days) at a single plant back interval of 0 days. In the different rotational crops investigated (wheat, turnip, spinach), IM-1-5 was shown to remain the main component of the radioactive residues accounting in mature plant at harvest for 77–94% TRR. Additional field rotational crop studies conducted in northern and southern EU with acetamiprid applied onto the bare soil at ca. 300 g/ha, confirmed that acetamiprid, IM-1-4 and IM-1-5 residues are not expected to be present in rotational crops.

However, the study: Hobbs, G., Inns, L., 2012: ¹⁴C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops, Report no. RD-02391 assessed in RAR is still protected.

A new study on the nature of residues in rotational crops was conducted for data matching purposes. Metabolism in succeeding crops was investigated with the IM-1-5. [¹⁴C]-IM-1-5 was applied on bare soil, supplied as [pyridyl-2,6-¹⁴C] decyano-acetamiprid hydrochloride, at a nominal rate of 0.266 kg/ha. The application rate of the study presented in the RAR (The Netherlands, 2015, 2016) was with the same dose

266 g a.s./ha. The seed used for this study was spring wheat, turnip and spinach. Minor uptake of IM-1-5 was observed for spinach and wheat grain. IM-1-5 residues within these sample types were below the 0.01 mg/kg. Some notable uptake of the test item was observed for wheat forage hay and straw. Residues were also detected in turnips above the 0.01 mg/kg. 24.68 % of the total radioactive residues remained bound to wheat hay and 22.26 % bound to wheat straw. However, uptake into the wheat hay, 22.26 % only represented 0.005 mg/kg. Only limited metabolism of IM-1-5 is observed in the crops and therefore no metabolic pathway is proposed. However, the study used sandy loam soil and not calcareous soil. It should be noted that according to the EFSA Journal 2016;14(11):4610 formation of metabolite IM-1-5 occurred only in the soils stated to be calcareous.

The Applicant did not provide a metabolism study taking into account alkaline soils. However, it should be noted that the residue definition covers only active substances and does not include any metabolites. It is the same for main and rotational crops. The results obtained from the Hobbs, G., Inns, L. (2012) study did not change the end points in this area. In addition in Poland only 9% of soils are alkaline. Therefore, **it seems that registration of CHR/I/ADEL 280 SC is possible in Poland with the reservation in the label that the product cannot be used on alkaline soils. However, the final decision should be made by risk managers.**

The Applicant provided additional explanations include comparison that demonstrate equivalence of the mentioned studies. zRMS accepts explanations. In the opinion of zRMS, the restriction previously indicated on the label is not required. However, the study presented by the Applicant should first be assessed in “Data matching studies for acetamiprid” to indicate that the studies are equivalent, so the final decision rests the risk managers.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Acetamiprid (0.1 mg/kg) 95.6% of the initial acetamiprid concentration Acetamiprid (1.0 mg/kg) 93.3% acetamiprid only	McMillan-Staff, Austin, D.J. 1997 [14C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. (unprotected study)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Acetamiprid (0.1 mg/kg) 95.1% of the initial acetamiprid concentration Acetamiprid (1.0 mg/kg) 95.6% acetamiprid only	
Sterilisation (20 minutes, 120°C, pH 6)	Acetamiprid (0.1 mg/kg) 98.1% of the initial acetamiprid concentration Acetamiprid (1.0 mg/kg) 97.6% acetamiprid only	
		The Netherlands, 2015, 2016 Greece, 2001 EFSA 2016

Conclusion on nature of residues in processed commodities

Acetamiprid is stable under standard hydrolysis conditions. Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites.

zRMS comments:

The residue definitions proposed for primary crops are also applicable for processed commodities.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and fruiting vegetable (Eggplant, Apple) Leafy vegetables (Cabbage) Root and tuber vegetables (Carrot) Pulses and oilseeds (Cotton)
Rotational crops covered	Leafy vegetables (Spinach) Root and tuber vegetables (Turnip) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	The only [¹⁴ C]-residue found in the crop commodities was IM-1-5 accounting for the entire extractable radioactive residue (≥ 76.8% TRR). No relevant metabolite was observed in any nature of residues in primary crop study.
Processed commodities	N/R Acetamiprid is stable under standard hydrolysis conditions.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes Pasteurisation, boiling and sterilisation are unlikely to result in any significant metabolites.
Plant residue definition for monitoring	Acetamiprid (EFSA Journal 2016;14(11):4610), EFSA Journal, 22(5), e8759, Reg. (EU) 2019/88 and not yet applicable SANTE/11278/2021 Reg. (EU) 2025/158 - Applicable from 19/08/2025 Reg. (EU) 2025/1212-applicable from 20/08/2025
Plant residue definition for risk assessment	Acetamiprid (EFSA Journal 2016;14(11):4610) EFSA Journal, 22(5), e8759: – Fruit crops: sum of acetamiprid and N-desmethyl acetamiprid (IM-2-1), expressed as acetamiprid – Leafy crops: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid – Pulses/oilseeds: acetamiprid – Root crops: acetamiprid – Cereals: acetamiprid
Conversion factor from enforcement to RA	not applicable (EFSA Journal 2016;14(11):4610) EFSA Journal, 22(5), e8759: Leafy crops: 1.44 Fruit crops: 1.21

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	Pyridine-2,6- ¹⁴ C	2	1 and 10	7	Milk	twice daily	(1997): ¹⁴ C-NI-25 (Acetamidrid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats. (unprotected study) The Netherlands, 2015, 2016 Greece, 2001 EFSA 2016
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Pyridine-2,6- ¹⁴ C	10	1 and 10	14	Eggs	daily	(1997): ¹⁴ C-NI-25 (Acetamidrid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Laying Hens. (unprotected study) The Netherlands, 2015, 2016 Greece, 2001 EFSA 2016
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Acetamiprid main component of residues (almost 50 to 99 % TRR), except in cabbage head and cotton seeds after foliar application where metabolite IC-0 (6- chloronicotinic acid) was detected as major (ca. 46 and 24 % TRR respectively). IC-0 was also present in carrot root at 26% TRR but in this case parent was the major residue.

Conclusion on metabolism in livestock

Since metabolism in rats and ruminants was demonstrated to be similar, the findings in ruminants can also be extrapolated to pigs.

Extensive elimination in the excreta (more than 95% of administered radioactivity) was observed for the two species. Acetamiprid extensively metabolised and only detected in milk. In all matrices residues identified as IM-2-1, except in goat muscle, where IM-2-2 was predominant, but at low levels (0.03 mg eq/kg)

zRMS comments:

According to the EFSA Journal 2016;14(11):4610: Metabolism studies on livestock conducted on animals dosed with 14 C-acetamiprid at 10 mg/kg dry matter (DM) over 7 (goat) or 17 (poultry) consecutive days were submitted. Most of the radioactivity was excreted in urine and faeces and only 2% of the administered radioactivity was recovered in organs, tissues, blood and milk or eggs. Acetamiprid was extensively metabolised and not detected in any animal matrices except in milk. The major component was identified as the N-desmethyl metabolite(IM-2-1) representing 50–89% TRR in all animal matrices, except goat muscle (10% TRR) where residues were mainly composed of the metabolite IM-2-2 accounting for 50% TRR (0.03 mg eq/kg).The metabolic profile was confirmed by the feeding studies on cow and poultry where IM-2-1 was detected as the most abundant component in all animal matrices. Acetamiprid was not present in poultry and only detected in significant levels in milk at all feeding levels and at the highest feeding level in the other matrices. Based on these studies, **the residue definition was proposed as ‘IM-2-1 expressed as acetamiprid’ for monitoring and as ‘the sum of acetamiprid and IM-2-1, expressed as acetamiprid’ for risk assessment.** Conversion factors (CF) of 1.3 and 1.1 were derived for milk and other mammalian products, respectively. CF values were concluded to be unnecessary for poultry products. It is highlighted that RMS expressed its disagreement on the livestock residue definition for risk assessment and proposes to include IM-2-1 compound only.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1-3 days to reach a steady state in milk
	4-8 days to reach a steady state in eggs
Animal residue definition for monitoring	Metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid EFSA Journal 2016;14(11):4610, Reg. (EU) 2019/88 and not yet applicable SANTE/11278/2021; Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid
Animal residue definition for risk assessment	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid EFSA Journal 2016;14(11):4610
Conversion factor	Milk: 1.3 Other mammalian products: 1.1 Poultry matrices: not required EFSA Journal 2016;14(11):4610 Not necessary

Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

zRMS comments:

Animal residue definition for monitoring currently implemented in the EU legislation (Reg. (EU) 2019/88) is sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid.

During the peer review for the renewal of the active substance acetamiprid (Journal 2016;14(11):4610), it was proposed to limit the residue definition for enforcement in animal commodities to metabolite IM-2-1 only, but this proposal was not further implemented in the MRL legislation.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of CHR/I/ADEL 280 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Winter oilseed rape	Paszek G., 2018, DPL/68/2018 Paszek G., 2018, DPL/70/2018 Paszek G., 2018, DPL/67/2018 Paszek G. 2020, DPL/131/2019 A. Augstynek, 2017, Study code: DPL/03/2017	NEU	New studies GAP: 1 application, BBCH: 69-79, 0.05 kg as/ha, PHI: 27-41 days, SE formulation E: 2x<0.012, 0.014, 0.015, 0.045, 0.087, 0.089, 0.093 RA: 2x<0.012, 0.014, 0.015, 0.045, 0.087, 0.089, 0.093	0.015	0.093	0.194 0.197	0.4 (Reg. (EU) 2025/158)	Yes
Winter wheat	Peda T., Jędrusik M. 2021	NEU	Grain: New studies GAP: 2 applications, BBCH: 75, BBCH 83, 0.04 kg as/ha, PHI: 24-37 E:, 4 x < 0.003, < 0.01	<0.003	<0.01	0.021 Too small dataset	0.1 (Reg. (EU) 2025/158)	Yes

	20SGS13 Peda T., Jędrusik M. 2021 20SGS15 Peda T., Jędrusik M. 2021 20SGS12 K. Wańczyk, 21SGS33 K. Wańczyk, 21SGS32		RA: $4x < 0.003$, < 0.01					
			Straw: New studies GAP: 2 applications, BBCH: 75, BBCH 83, 0.04 kg as/ha, PHI: 24-37 E: $5x < 0.003$ RA: $5 < 0.003$	0.047	0.29	-	-	-
Formulation SC								
Winter wheat	Peda, T., Głowiak, K., 2024, 23SGS35, Peda, T., Głowiak, K., 2024, 23SGS37, Peda, T., Głowiak, K., 2024, 23SGS38, Peda, T., Niewelt- Stasiak, S., 2024, 23SGS39	NEU	Grain: New studies GAP: 1 application, BBCH: 77-79, 0.04 kg as/ha, PHI: 25-35 E: $4x < 0.005$ RA: $4x < 0.005$	< 0.005	< 0.005	0.015	0.1 (Reg. (EU) 2025/158)	Yes
		NEU	Straw: New studies GAP: 1 application, BBCH: 77-79, 0.04 kg as/ha, PHI: 25-35 E: 0.076, 0.086, 0.10, 0.26 RA: 0.076, 0.086, 0.10, 0.26	0.093	0.26	!	!	!
Sugar beet	Peda T., Paszek G. 2021 20SGS29	NEU	Roots: New Studies GAP: 1 application, BBCH 19, 2 x 40g a.s./ha, PHI 66, 96 E: $4x < 0.003$ RA: $4x < 0.003$	< 0.003	< 0.003	0.009 0.003	0.01 (Reg. (EU) 2025/158)	Yes

	Peda T., Paszek G. 2021 20SGS30 Wanczyk, K. 21SGS26 Wanczyk, K. 21SGS27		Leaves: : New Studies GAP: 1 application, BBCH 19, 2 x 40g a.s./ha, PHI 66, 96 E: 4 x <0.003 RA:4 x <0.003	<0.003	<0.003	-	-	-
Formulation SC								
Sugar beet	Peda, T., Głowiak, K., 2024, 23SGS40, Peda, T., Głowiak, K., 2024, 23SGS42, Peda, T., Niewelt- Stasiak, S., 2024, 23SGS43, Peda, T., Niewelt- Stasiak, S., 2024, 23SGS44	NEU	Roots: New Studies GAP: 1 application, BBCH 19, 40g a.s./ha, PHI 57-107 E: 4 x <0.001 RA:4 x <0.001	<0.001	<0.001	0.003 0.001	0.01 (Reg. (EU) 2025/158)	Yes
		NEU	Leaves: : New Studies GAP: 1 application, BBCH 19, 40g a.s./ha, PHI 57-107 E: 4 x <0.001 RA:4 x <0.001	<0.001	<0.001	!	!	!
Honey	Lefebvre, C., 2022, C0280, Lefebvre, C., 2021, C0281, Lefebvre, C., 2022, C1063	EU	GAP: 2 x 0.10 kg as/ha, BBCH 63-67, PHI 7-d, outdoor E: <0.01, 0.01, 0.05, 0.09 RA: <0.01, 0.01, 0.05, 0.09	N/A				

	Lefebvre, C., 2022, C1064							
	Overall supporting data for cGAP	EU	E: <0.01, 0.01, 0.05, 0.09 RA: <0.01, 0.01, 0.05, 0.09	0.03	0.09	0.193	0.3 (Reg- (EU) 2025/158) 0.05 0.3	Yes No Yes

* Source of EU MRL: Regulation (EU) 2019/88, Regulation (EU) 2025/158 applicable from 19/08/2025 includes a proposal for an MRL in honey of 0.05 mg/kg,
 Regulation (EU) 2025/1212 applicable from 20/08/2025

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on winter oilseed rape, winter cereal and sugar beets are considered acceptable, for both indoor and outdoor uses.

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS comments:

Acetamiprid

Wheat

EU GAP, EFSA Journal 2016;14(2):4385:

2 appl., interval 14 days, BBCH 51-79, max appl. rate per treatment 42 g a.s./ha, PHI-28 days, SL formulation

Intended GAP: 1 appl., BBCH 37-75, max appl. rate 40 g a.s./ha, SC formulation

The Applicant provided 5 studies performed for the SE formulation and 4 for the SC formulation. Most of them (all but two studies for SE formulation) are not covered by stability studies for wheat grain. The storage period ranges from 155 to 192 days for wheat grain, while stability studies were performed for a maximum of 149 days in this matrices. Taking the above into account, the results of the presented studies cannot support the proposed use in wheat.

The proposed uses on wheat and triticale are not accepted.

All studies showed no acetamiprid residues above LOQ in cereal grain.

The data submitted show that no exceedance of the MRL will occur.

Residues of acetamiprid in straw (SC formulation): 0.076, 0.086, 0.1, 0.26 mg/kg.

Residues of acetamiprid in straw (SE formulation): < 0.01, 0.047, 0.066, 0.29, 0.52 mg/kg

The use is considered acceptable.

Sugar beet

Intended GAP

1 appl., BBCH 12-19, max appl. rate 40 g a.s./ha, SC formulation

The Applicant provided 4 studies performed for the SE formulation and 4 for the SC formulation. All presented studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no acetamiprid residues above LOD in both leaves and roots.

The data submitted show that no exceedance of the MRL will occur.

The use is considered acceptable.

Rapeseed

GAP assessed at EU level:

EFSA Journal 2011;9(7):2328: formulation SG,

1 appl., BBCH 75-81, max appl. rate 50 g a.s./ha, PHI-28,

Residues of acetamiprid in seeds harvested at the PHI: 3 x <0.01; 0.03; 0.04; 2 x 0.08; 0.1 (STMR 0.035 mg/kg)

EFSA Journal 2016;14(2):4385:

2 appl., 1st appl. BBCH 59, 2nd appl. BBCH 80, max appl. rate per treatment 42 g a.s./ha, PHI- n.r.,

two different formulations were investigated (SL and SG) and the highest residue level from these two formulations was selected for MRL calculation.

Residues of acetamiprid in seeds harvested at the PHI ranging from 26 to 43 days: < 0.01; 2 x 0.02;

0.021; 0.036; 0.05; 0.11; 0.20 (STMR 0.036 mg/kg)

Intended cGAP: formulation SC, 1 appl., BBCH 30-70, max appl. rate 40 g a.s./ha

The Applicant provided 8 studies performed for the SE formulation. All presented studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application.

Residues of acetamiprid in seeds harvested at the PHI 39-45: 2 x <0.012; 0.014; 0.015; 0.045; 0.087; 0.089; 0.093 (STMR 0.03 mg/kg).

The data submitted show that no exceedance of the MRL will occur. However, it should be noted that the Applicant did not provide field studies with SC formulation. Taking into account that the STMR values from the studies presented for the SE formulation are very close to the results from studies assessed at EU level for the SG and SL formulations and that the residue results are much lower than the applicable MRL value, the MRL in force should not be expected to be exceeded also for SC formulation. In the opinion of zRMS, authorisation based on the data provided is therefore possible, but the final decision should be made by risk managers. Please indicate PHI equal to 45 days.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized within the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: Acetamiprid				
Sugar beet, tops	0.003	STMR/HR	N/A	
Rape, forage	0.02 0.09	STMR HR	N/A	
Triticale, forage	0.09 0.26	STMR HR	N/A	
Triticale, hay	0.27 0.75	0.09 (STMR) × 2.9 (PF) 0.26 (HR) × 2.9 (PF)	N/A	
Triticale, straw	0.09 0.26	STMR HR	N/A	
Wheat, forage	0.09 0.26	STMR HR	N/A	
Wheat, hay	0.33 0.91	0.09 (STMR) × 3.5 (PF) 0.26 (HR) × 3.5 (PF)	N/A	
Wheat, straw	0.09 0.26	STMR HR	N/A	

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Triticale, grain	0.01	STMR	N/A	
Wheat, grain	0.01	STMR	N/A	
Sugar beet, dried pulp	0.05	$0.003 \text{ (STMR)} \times 18 \text{ (PF)}$	N/A	
Sugar beet, ensiled pulp	0.01	$0.003 \text{ (STMR)} \times 3 \text{ (PF)}$	N/A	
Sugar beet, molasses	0.08	$0.003 \text{ (STMR)} \times 28 \text{ (PF)}$	N/A	
Canola, meal	0.03	$0.015 \text{ (STMR)} \times 2 \text{ (PF)}$	N/A	
Distiller's grain	0.03	$0.01 \text{ (STMR)} \times 3.3 \text{ (PF)}$	N/A	
Rape, meal	0.03	$0.015 \text{ (STMR)} \times 2 \text{ (PF)}$	N/A	
Wheat, gluten meal	0.02	$0.01 \text{ (STMR)} \times 1.8 \text{ (PF)}$	N/A	
Wheat, mill by-pdts	0.07	$0.01 \text{ (STMR)} \times 7 \text{ (PF)}$	N/A	

New calculations were presented below in Animal model 2017.

Animal burden calculation										Acetamiprid														
According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"																								
Cattle										Sheep														
Beef					Dairy					Ram/Ewe					Lamb									
500 kg 12 kg					650 kg 25 kg					75 kg 2.5 kg					40 kg 1.7 kg									
Maximum Intake					Maximum Intake					Maximum Intake					Maximum Intake									
(mg/kg bw/d)					(mg/kg bw/d)					(mg/kg bw/d)					(mg/kg bw/d)									
Contributor 1	Wheat	forage	20		Contributor 1	Wheat	forage	20		Contributor 1	Wheat	forage	40		Contributor 1	Wheat	forage	30						
Contributor 2	Beet, sugar	ensiled pulp	25		Contributor 2	Beet, sugar	ensiled pulp	40		Contributor 2	Beet, sugar	dried pulp	40		Contributor 2	Beet, sugar	dried pulp	40						
Contributor 3	Triticale	grain	40		Contributor 3	Triticale	grain	40		Contributor 3	Triticale	grain	20		Contributor 3	Triticale	grain	30						
Contributor 4					Contributor 4					Contributor 4					Contributor 4									
Median intake	0.0022	mg/kg bw/d			Median intake	0.0039	mg/kg bw/d			Median intake	0.0055	mg/kg bw/d			Median intake	0.0059	mg/kg bw/d							
Swine										Intakes >0.004 mg/kg bw/d are highlighted														
Breeding					Finishing																			
260 kg 6 kg					100 kg 3 kg																			
Maximum Intake					Maximum Intake																			
(mg/kg bw/d)					(mg/kg bw/d)																			
Contributor 1	Wheat	forage	20		Contributor 1	Wheat	milled bypdf	50																
Contributor 2	Wheat	milled bypdf	50		Contributor 2	Triticale	grain	50																
Contributor 3	Triticale	grain	30		Contributor 3																			
Contributor 4					Contributor 4																			
Median intake	0.002	mg/kg bw/d			Median intake	0.001	mg/kg bw/d																	
Poultry																								
Broiler					Layer					Turkey														
1.7 kg 0.12 kg					1.3 kg 0.13 kg					7 kg 0.5 kg														
Maximum Intake					Maximum Intake					Maximum Intake														
(mg/kg bw/d)					(mg/kg bw/d)					(mg/kg bw/d)														
Contributor 1	Wheat	milled bypdf	20		Contributor 1	Wheat	forage	10		Contributor 1	Wheat	milled bypdf	20											
Contributor 2	Wheat	grain	70		Contributor 2	Wheat	milled bypdf	20		Contributor 2	Wheat	grain	50											
Contributor 3					Contributor 3	Wheat	grain	70		Contributor 3														
Contributor 4					Contributor 4					Contributor 4														
Median intake	0.001	mg/kg bw			Median intake	0.003	mg/kg bw			Median intake	0.001	mg/kg bw												
Intakes expressed on the dry mater basis (mg/kg DM)																								
Cattle					Sheep					Swine														
Beef					Dairy					Ram/Ewe					Lamb									
Maximum					Maximum					Maximum					Maximum									
Median					Median					Median					Median									
0.2252					0.23					0.44					0.34									
0.0916					0.10					0.17					0.14									
Poultry										Intake >0.1 mg/kg DM in red characters														
Broiler					Layer															Turkey				
Maximum					Maximum															Maximum				
Median					Median					Median														
0.01					0.12					0.01														
0.01					0.05					0.01														

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Three groups of lactating cows, each consisting of three animals, were dosed for 28 days with acetamiprid at levels of 0.21, 0.63 and 2.13 mg acetamiprid/kg bw/day. The samples were analyzed for parent acetamiprid and IM-2-1. IM-2-1 was the dominant residue in all tissues and in whole milk. Both parent compound and IM-2-1 metabolite were highly dose-dependent in all tissues collected at day 28. In whole milk, IM-2-1 reached a plateau by the seventh day of dosing. For poultry, no livestock feeding study is available but the metabolism study in laying hens was performed at dose levels of approximately 12

mg/kg feed.

Residues from livestock feeding studies (EFSA Journal 2016;14(11):4610)

MRL calculations	Ruminant			Pig/Swine		Poultry		Fish		
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) Intake >0.004 mg/kg bw Feeding study submitted	Beef cattle	0.001	Ram/Ewe	0.002	Breeding	0.001	Broiler	0.001	Carp	Not required
	Dairy cattle	0.002	Lamb	0.001	Finishing	0.001	Layer	0.000	Trout	Not required
							Turkey	0.001	Fish intake >0.1 mg/kg DM	
	No		No		No		No		N/A	
	Yes, Lactating cow, 28-day						Yes, Laying hens, 28-day		N/A	

Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Residue definition for enforcement and risk assessment: sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid												
Pig meat	0.007	0.024	0.21	3	0.05	0.05	See results for enforcement residue definition	0.02	0.02	0.02* (tentative)	1.00	
			0.63	3	0.18	0.29						
			2.13	3	0.97	1.11						
Pig fat			0.21	3	0.03	0.06		0.02	0.02	0.02* (tentative)	1.00	
			0.63	3	0.07	0.15						
			2.13	3	0.36	0.71						
Pig liver			0.21	3	0.15	0.15		0.10	0.10	0.1* (tentative)	1.00	
			0.63	3	0.45	0.64						
			2.13	3	2.29	2.65						
Pig kidney			0.21	3	0.24	0.25		0.10	0.10	0.1* (tentative)	1.00	
			0.63	3	0.70	0.86						
			2.13	3	2.39	2.54						
Ruminant meat	0.034	0.088	0.21	3	0.05	0.05		0.02	0.02	0.05 (tentative)	1.00	
			0.63	3	0.18	0.29						
			2.13	3	0.97	1.11						
Ruminant fat			0.21	3	0.03	0.06		0.02	0.03	0.05 (tentative)	1.00	
			0.63	3	0.07	0.15						

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ruminant liver			2.13	3	0.36	0.71			0.10	0.10	0.1* (tentative)	1.00
			0.21	3	0.15	0.15						
			0.63	3	0.45	0.64						
			2.13	3	2.29	2.65						
Ruminant kidney			0.21	3	0.24	0.25			0.10	0.11	0.2 (tentative)	1.00
			0.63	3	0.70	0.86						
			2.13	3	2.39	2.54						
Milk	0.016	0.075	0.21	n.p.	0.08 ^(a)	n.a.			0.02	0.03	0.05 (tentative)	1.00
			0.63	n.p.	0.37 ^(a)	n.a.						
			2.13	n.p.	1.30 ^(a)	n.a.						

n.a.: not applicable – only the mean values are considered for calculating MRLs in milk

n.p.: not precised

(*) Indicates that the MRL is set at the limit of analytical quantification.

(a): mean residue level from day -1 until day 27 (3 cows, 11 sampling days)

No new data were submitted in the framework of this application.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Data/information on processing studies was reviewed during the approval of active substance(s) and were considered acceptable.

7.2.5.1 Available data for all crops under consideration

No new data regarding magnitude of residues in processed commodities is considered necessary, because residue level in all studies does not exceed 0.1 mg/kg.

Table 7.2-11: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Not required					

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.2.5.2 Conclusion on processing studies

Not required

zRMS comments:

No new data were submitted in the framework of this application.

According to the EFSA Journal 2016;14(2):4385: The effect of processing on the nature of acetamiprid residues was investigated and the results indicated that acetamiprid is hydrolytically stable under standard hydrolysis conditions (Greece, 2001; EFSA, 2011). Thus, residue definitions proposed for primary crops are also applicable for processed commodities.

Some residue trials on olives and gherkins were performed at exaggerated dose rates (10x and 5x, respectively) to generate samples for processing studies (Greece, 2015b). Olives were processed into canned olives or raw oil; the relevant intermediate products – cake and brine – were also analysed for residues. Gherkins were canned; in two trials, washed gherkins and brine were also analysed for residues. However, no details of the processing conditions were provided. A reduction of residues is observed in all processed edible commodities: canned olives, raw olive oil and canned gherkins.

According to Regulation (EU) 283/2013 processing studies are required if residues in plants to be processed are ≥ 0.1 mg/kg. If the level of residues is < 0.1 mg/kg, processing studies shall be carried out if the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is $\geq 10\%$ of the ADI or if the estimated daily intake is $\geq 10\%$ of the ARfD for any European consumer group

diet.

Wheat

No residues above 0.1 mg/kg were found and TMDI is <10% of the ADI and IESTI is < 10% of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

Oilseed rape

No residues above 0.1 mg/kg (HR = 0.093 mg/kg) were found and TMDI is <10% of the ADI and IESTI is < 10% of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

Sugar beet

No residues above 0.1 mg/kg were found and TMDI is <10% of the ADI and IESTI is < 10% of ARfD. Therefore, processing studies are not required as they are not expected to affect the outcome of the risk assessment significantly.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are have been submitted and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

New studies for residues in succeeding crops have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

Table 7.2-12: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
New data					
Bare soil	300 g a.s./ha	Leafy vegetables	Spinach	30±2 70±3 120±3 365±5	Palau I., 2021, FIELD ROTATIONAL CROP STUDY (SPRING CEREAL, SPINACH AND TURNIPS) WITH A SUSPO EMULSION FORMULATION CONTAINING 200 G/L ACETAMIPRID APPLIED TO
	300 g a.s./ha	Root and tuber vegetables	Turnip	30±2 70±3 120±3 365±5	
	300 g a.s./ha	Pulses and oilseeds	Spring cereal	30±2 70±3 120±3 365±5	

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
					BARE SOIL AT 365, 120, 70 AND 30 DAYS PRIOR TO PLANTING THE ROTATIONAL CROPS IN THE UNITED KINGDOM AND SPAIN, 2019/2020 AC19- 002

Conclusion on rotational crops studies

Residues of acetamiprid and IM-1-5 were less than the LOQ in all crop matrices for both trial sites. Residues of IM-1-4 were less than the LOQ in all crop matrices in Spain, except in one spring cereal sample (at 0.024 mg/kg) and one turnip sample (0.010 mg/kg). Residues of IM-1-4 were less than the LOQ in all crop matrices in the United Kingdom, except one spinach sample (at 0.011 mg/kg) and seven turnip samples which ranged from 0.012 – 0.021 mg/kg.

zRMS comments:

According to the EFSA Journal 2018;16(5):5262: Field studies in NEU and SEU conducted at ca 300 g/ha on bare soil showed that no residues are expected in rotational crops.

Considering that the conditions of application of the representative uses assessed during the renewal and in the new provided by the Applicant study cover the intended use of acetamiprid in CHR/I/ADEL 280 SC, this conclusion is still relevant in the framework of the present assessment.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

Sugar beet, wheat and triticale have no melliferous capacity therefore magnitude of residues in honey are not necessary in accordance to SANTE/11956/2016 rev. 9 14 September 2018.

For spring winter oilseed rape application new magnitude of residues in honey were provided to support submission of the documentation of product CHR/I/ADEL 280 SC.

Risk from autumn application in winter oilseed rape is negligible, therefore no magnitude of residue studies are necessary to support this use in applicant's opinion.

Table 7.2-14: Summary of EU reported and new data supporting the intended uses of CHR/I/ADEL and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Honey	Lefebvre, C., 2022, C0280, Lefebvre, C., 2021, C0281, Lefebvre, C., 2022, C1063, Lefebvre, C., 2022, C1064	EU	GAP: 2 x 0.10 kg as/ha, BBCH 63-67, PHI 7-d, outdoor E: <0.01, 0.01, 0.05, 0.09 RA: <0.01, 0.01, 0.05, 0.09	N/A				
	Overall supporting data for cGAP	EU	RA: <0.01, 0.01, 0.05, 0.09	0.03	0.09	0.193 0.2(rounded)	0.3* 0.05 1.0* 0.3	Yes No Yes

*EFSA Journal 2022;20(8):7535 Reg.(EU) 2019/88 EFSA Journal. 2025;23:e9300, Reg. (EU) 2025/1212

The results of residues in honey do not exceed both MRL values proposed and supported by EFSA decision in *EFSA Journal* 2022;20(8):7535 (0.3 and 2.0 mg/kg). Considering that studies were performed in overdosed application rate (2x 100g instead of 1x 40g a.s./ha), no unacceptable risk should be expected while applying product during the flowering period on melliferous crop.

zRMS comments:

Based on the study provided by the Applicant, it can be concluded that residues in honey would lead to a calculated MRL of 0.2 mg/kg by using the new EU MRL calculator of 2015. One of the results exceeds the currently applicable MRL value, i.e. 0.05 mg/kg.

In accordance with Article 6 of Regulation (EC) No 396/2005, the Nufarm Europe GmbH submitted a request to the competent national authority in Austria to modify the existing maximum residue levels (MRLs) for acetamiprid in honey.

According to the EFSA Journal 2022;20(8):7535: EFSA proposes to amend the existing MRL for honey. Risk Managers are given the options to either set an MRL for honey of 2 mg/kg based on the four residue trials provided with the current application (despite the deviation of not having control samples for two trials) or merge two data sets to derive an MRL of 0.3 mg/kg based on six residue trials performed in accordance with the requirements of the honey guidelines. Risk for consumers unlikely for both MRLs proposed.

Based on EFSA opinion, a draft regulation (SANTE/11278/2021) amending the MRL value for honey is now available.

In line with EFSA Journal, 22(5), e8759 which proposed lowering toxicological reference values (ADI and ARfD): For honey, it was concluded that risk for consumers was still unlikely for the new MRLs (0.3 mg/kg), proposed in SANTE/11278/2021. Risk managers can therefore implement the MRLs proposed in SANTE/11278/2021.

According to the Reg. (EU) 2025/1212 (applicable from 20/08/2025), the MRL value for acetamiprid in

honey has been raised to 0.3 mg/kg.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: Acetamiprid				
TMDI input values				
Rapeseeds/canola seeds	0.4	EU MRL Reg. (EU) 2025/158	0.4	EU MRL Reg. (EU) 2025/158
Wheat	0.1	EU MRL Reg. (EU) 2025/158	0.1	EU MRL Reg. (EU) 2025/158
Other cereals	0.1	EU MRL Reg. (EU) 2025/158	0.1	EU MRL Reg. (EU) 2025/158
Sugar beet roots	0.01	EU MRL Reg. (EU) 2025/158	0.01	EU MRL Reg. (EU) 2025/158
Rapeseed, oils	0.8	MRL × PF Reg. (EU) 2025/158	0.8	MRL × PF Reg. (EU) 2025/158
Wheat, bread (wholemeal)	0.1	MRL × PF Reg. (EU) 2025/158	0.1	MRL × PF Reg. (EU) 2025/158
Wheat, bread/ pizza	0.1	MRL × PF Reg. (EU) 2025/158	0.1	MRL × PF Reg. (EU) 2025/158
Wheat, pasta	0.1	MRL × PF Reg. (EU) 2025/158	0.1	MRL × PF Reg. (EU) 2025/158
Wheat, milling (wholemeal)-baking	0.1	MRL × PF Reg. (EU) 2025/158	0.1	MRL × PF Reg. (EU) 2025/158
Wheat, milling (flour)	0.1	MRL × PF Reg. (EU) 2025/158	0.1	MRL × PF Reg. (EU) 2025/158
Swine: Muscle/meat	0.500	EU MRL Reg. (EU) 2025/158	0.500	EU MRL Reg. (EU) 2025/158
Swine: Fat tissue	0.300	EU MRL Reg. (EU) 2025/158	0.300	EU MRL Reg. (EU) 2025/158
Swine: Liver	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Kidney	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Swine: Edible offals (other than liver and kidney)	1.000	MRL × PF Reg. (EU) 2025/158	1.000	MRL × PF Reg. (EU) 2025/158
Swine: Other products	0.02	EU MRL Reg. (EU) 2025/158	0.02	EU MRL Reg. (EU) 2025/158
Bovine: Muscle/meat	0.500	EU MRL Reg. (EU) 2025/158	0.500	EU MRL Reg. (EU) 2025/158
Bovine: Fat tissue	0.300	EU MRL Reg. (EU) 2025/158	0.300	EU MRL Reg. (EU) 2025/158
Bovine: Liver	0.03	EU MRL Reg. (EU) 2025/158	0.03	EU MRL Reg. (EU) 2025/158
Bovine: Kidney	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Bovine: Edible offals (other than liver and kidney)	0.05	EU MRL Reg. (EU) 2025/158	0.05	EU MRL Reg. (EU) 2025/158
Bovine: Other products	0.02	EU MRL Reg. (EU) 2025/158	0.02	EU MRL Reg. (EU) 2025/158
Sheep: Muscle/meat	0.500	EU MRL Reg. (EU) 2025/158	0.500	EU MRL Reg. (EU) 2025/158
Sheep: Fat tissue	0.300	EU MRL Reg. (EU) 2025/158	0.300	EU MRL Reg. (EU) 2025/158
Sheep: Liver	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Sheep: Kidney	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Sheep: Edible offals (other than liver and kidney)	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Sheep: other products	0.02	EU MRL Reg. (EU) 2025/158	0.02	EU MRL Reg. (EU) 2025/158
Goat: Muscle/meat	0.500	EU MRL Reg. (EU) 2025/158	0.500	EU MRL Reg. (EU) 2025/158
Goat: Fat tissue	0.300	EU MRL Reg. (EU) 2025/158	0.300	EU MRL Reg. (EU) 2025/158
Goat: Liver	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Goat: Kidney	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Goat: Edible offals (other than liver and kidney)	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Goat: other products	0.02	EU MRL Reg. (EU) 2025/158	0.02	EU MRL Reg. (EU) 2025/158
Equine: Muscle/meat	0.500	EU MRL Reg. (EU) 2025/158	0.500	EU MRL Reg. (EU) 2025/158
Equine: Fat tissue	0.300	EU MRL Reg. (EU) 2025/158	0.300	EU MRL Reg. (EU) 2025/158
Equine: Liver	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Equine: Kidney	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Equine: Edible offals (other than liver and kidney)	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Equine: Other products	0.02	EU MRL Reg. (EU) 2025/158	0.02	EU MRL Reg. (EU) 2025/158
Poultry: Muscle/meat	0.020	EU MRL Reg. (EU) 2025/158	0.020	EU MRL Reg. (EU) 2025/158
Poultry: Fat tissue	0.020	EU MRL Reg. (EU) 2025/158	0.020	EU MRL Reg. (EU) 2025/158
Poultry: Liver	0.100	EU MRL Reg. (EU) 2025/158	0.100	EU MRL Reg. (EU) 2025/158
Poultry: Kidney	0.100	EU MRL Reg. (EU) 2025/158	0.100	EU MRL Reg. (EU) 2025/158
Poultry: Edible offals (other than liver and kidney)	0.020	EU MRL Reg. (EU) 2025/158	0.020	EU MRL Reg. (EU) 2025/158
Poultry: Other products	0.020	EU MRL Reg. (EU) 2025/158	0.020	EU MRL Reg. (EU) 2025/158
Other farmed animals: Muscle/meat	0.500	EU MRL Reg. (EU) 2025/158	0.500	EU MRL Reg. (EU) 2025/158
Other farmed animals: Fat tissue	0.300	EU MRL Reg. (EU) 2025/158	0.300	EU MRL Reg. (EU) 2025/158
Other farmed animals: Liver	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Other farmed animals: Kidney	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Other farmed animals: Edible offals (other than liver and kidney)	1.000	EU MRL Reg. (EU) 2025/158	1.000	EU MRL Reg. (EU) 2025/158
Other farmed animals: Other products	0.020	EU MRL Reg. (EU) 2025/158	0.020	EU MRL Reg. (EU) 2025/158
Milk: Cattle	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Milk: Sheep	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Milk: Goat	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Milk: Horse	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Milk: Others	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Eggs: Chicken	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Eggs: Duck	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Eggs: Goose	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Eggs: Quail	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Eggs: Others	0.200	EU MRL Reg. (EU) 2025/158	0.200	EU MRL Reg. (EU) 2025/158
Honey and other apiculture products	0.3 1.0	EU MRL EFSA Journal, 2025;23:e9300	0.3 1.0	EU MRL EFSA Journal, 2025;23:e9300
IED/UESTI				
Rapeseeds/canola seeds	1	1	0.015	STMR
Wheat	1	1	0.003	STMR
Other cereals	1	1	0.003	STMR
Sugar beet roots	1	1	0.003	STMR
Rapeseed, oils	1	1	0.03	STMR × PF
Wheat, bread (wholemeal)	1	1	0.003	STMR
Wheat, bread/ pizza	1	1	0.003	STMR
Wheat, pasta	1	1	0.003	STMR
Wheat, milling (wholemeal)-baking	1	1	0.003	STMR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat, milling (flour)	0.003	STMR	0.003	STMR
Sugar beets (root)/ sugar	0.036	STMR	0.036	STMR
Swine: Muscle/meat	0.010	STMR	0.010	HR
Swine: Fat tissue	0.010	STMR	0.010	HR
Swine: Liver	0.020	STMR	0.030	HR
Swine: Kidney	0.020	STMR	0.040	HR
Bovine: Muscle/meat	0.010	STMR	0.010	HR
Bovine: Fat tissue	0.010	STMR	0.010	HR
Bovine: Liver	0.020	STMR	0.030	HR
Bovine: Kidney	0.020	STMR	0.040	HR
Sheep: Muscle/meat	0.010	STMR	0.010	HR
Sheep: Fat tissue	0.010	STMR	0.010	HR
Sheep: Liver	0.020	STMR	0.030	HR
Sheep: Kidney	0.020	STMR	0.040	HR
Goat: Muscle/meat	0.010	STMR	0.010	HR
Goat: Fat tissue	0.010	STMR	0.010	HR
Goat: Liver	0.020	STMR	0.030	HR
Goat: Kidney	0.020	STMR	0.040	HR
Equine: Muscle/meat	0.010	STMR	0.010	HR
Equine: Fat tissue	0.010	STMR	0.010	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Equine: Liver	0.020	STMR	0.030	HR
Equine: Kidney	0.020	STMR	0.040	HR
Milk: Cattle	0.02	STMR	-	-
Milk: Sheep	0.02	STMR	-	-
Milk: Goat	0.02	STMR	-	-
Milk: Horse	0.02	STMR	-	-
Milk: Others	0.02	STMR	-	-
Honey and other apiculture products	0.03	STMR	0.09	HR

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

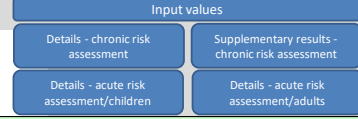
Table 7.2-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	56% for milk (based on NL toddler) 7% for wheat (based on GEMS/Food G06) 99% for milk cattle (based on children) 5% for wheat, milling (wholemeal) (based on children)	280% for milk:cattle (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	53% for milk (based on NL toddler) 0.1% for wheat (based on IT toddler)	32% for wheat (based on GEMS/Food G06)
IESTI (% ARfD) according to EFSA PRIMo*	1% sugar beets (roots)/ sugar (based on children)	27% for milk:cattle (based on NL toddler)
ADI	0.025 mg/kg bw per day	0.5% for wheat (based on IT toddler)
ARfD	0.025 mg/kg bw	64% for other farmed animals (based on children)

* include raw and processed commodities if both values are required for PRIMo

The proposed uses of Acetamiprid in the formulation do not represent unacceptable acute and chronic risks for the consumer.

In addition, TMDI calculation was performed taking into account the applicable EU MRLs (Reg. (EU) 2019/88) for the intended crops and all products of animal origin, except for honey, where the new proposed MRL have been considered.



For IESTI calculation the current EU MRLs were used for the intended crops, except for honey, where the new proposed MRL have been considered.

Acute risk assessment /children

Acute risk assessment / adults / general population

Details - acute risk assessment /children

Details - acute risk assessment /adults

Hide IESTI new calculations

Show IESTI new calculations

The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

ESTI new calculations:

The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children

No. of commodities for which ARID/ADI is exceeded (IESTI):

IESTI

Highest % of ARID/ADI

Commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

6%

Wheat

0.1 / 0.1

1.4

2%

Rapeseeds/canola seeds

0.4 / 0.4

0.55

Results for adults

No. of commodities for which ARID/ADI is exceeded (IESTI):

IESTI

Highest % of ARID/ADI

Commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

3%

Wheat

0.1 / 0.1

0.84

0.8%

Rapeseeds/canola seeds

0.4 / 0.4

0.21

ESTI new

Results for children

No. of commodities for which ARID/ADI is exceeded (IESTI new):

IESTI new

Highest % of ARID/ADI

Commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

6%

Wheat

0.1 / 0.1

1.4

2%

Rapeseeds/canola seeds

0.4 / 0.4

0.55

ESTI new

Results for adults

No. of commodities for which ARID/ADI is exceeded (IESTI new):

IESTI new

Highest % of ARID/ADI

Commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

3%

Wheat

0.1 / 0.1

0.84

0.8%

Rapeseeds/canola seeds

0.4 / 0.4

0.21

Expanded/collapse list

Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children

No. of processed commodities for which ARID/ADI is exceeded (IESTI):

IESTI

Highest % of ARID/ADI

Processed commodities

MRL / input for RA (mg/kg)

Exposure (µg/kg bw)

5%

Wheat / milling (flour)

0.1 / 0.1

1.2

2%

Sugar beets (root) / sugar

0.01 / 0.12

1.1

2%

Wheat / milling (wholemeal)

0.1 / 0.1

0.55

0.9%

Rapeseeds / oils

0.4 / 0.8

0.24

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TMDI (% ADI) according to EFSA PRIMo 3.1	56% for milk (based on NL toddler) 7% for wheat (based on GEMS/Food G06) 99% for milk cattle (based on children) 5% for wheat, milling (wholemeal) (based on children)
IESTI (% ARfD) according to EFSA PRIMo3.1	6% wheat 2% rapeseeds Processed commodities 5% whet/milling (flour) 4% sugar beets (root)/sugar 0.9% rapeseeds/oils

The proposed uses of Acetamiprid in CHR/I/ADEL 280 SC do not represent unacceptable acute and chronic risks for the consumer.

Calculations were also made taking into account the reduced ADI and ARfD values proposed in EFSA Journal, 22(5), e875.

The chronic risk assessment was performed taking into account the applicable EU MRLs (Reg. (EU) 2019/88) for the intended crops, except for honey, where the new proposed MRL have been considered and STMR values given in EFSA Journal 2018;16(5):5262 for products of animal origin.

 <p>European Food Safety Authority</p> <p>EFSA PRIMo revision 3.1; 2021/01/06</p>		<div>Acetamiprid</div> <div>LOQs (mg/kg) range from: to:</div> <div>Toxicological reference values</div> <div>ADI (mg/kg bw/day): 0.005 ARfD (mg/kg bw): 0.005</div> <div>Source of ADI: Source of ARfD:</div> <div>Year of evaluation: Year of evaluation:</div>		<div>Input values</div> <div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>							
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
No. of diets exceeding the ADI: ---											
TMDI/IED/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Commodities not under assessment (in % of ADI)
	43%	NL toddler	2.19	24%	Milk: Cattle	8%	Wheat	8%	Rapeseeds/canola seeds		
	25%	NL child	1.26	10%	Milk: Cattle	8%	Wheat	4%	Rapeseeds/canola seeds		
	23%	UK infant	1.16	15%	Milk: Cattle	5%	Wheat	0.5%	Eggs: Chicken		
	22%	FR child 3-15 yr	1.12	9%	Wheat	5%	Milk: Cattle	0.7%	Sugar beet roots		
	21%	FR toddler 2-3 yr	1.04	12%	Milk: Cattle	6%	Wheat	0.6%	Sugar beet roots		
	18%	DE child	0.91	8%	Wheat	8%	Milk: Cattle	0.6%	Honey and other apiculture products		
	18%	UK toddler	0.91	8%	Milk: Cattle	8%	Wheat	0.6%	Sugar beet roots		
	17%	GEMS/Food G07	0.87	8%	Wheat	4%	Rapeseeds/canola seeds	3%	Milk: Cattle		
	17%	ES child	0.85	9%	Wheat	5%	Milk: Cattle	0.8%	Other farmed animals: Muscle/meat		
	17%	GEMS/Food G06	0.84	14%	Wheat	1.0%	Milk: Cattle	0.3%	Sugar beet roots		
	16%	RO general	0.82	10%	Wheat	5%	Milk: Cattle	0.5%	Swine: Muscle/meat		
	16%	DK child	0.81	9%	Wheat	5%	Milk: Cattle	0.9%	Swine: Muscle/meat		
	15%	GEMS/Food G15	0.77	9%	Wheat	3%	Milk: Cattle	2%	Rapeseeds/canola seeds		
	15%	GEMS/Food G08	0.74	8%	Wheat	3%	Rapeseeds/canola seeds	2%	Milk: Cattle		
	14%	GEMS/Food G10	0.69	8%	Wheat	2%	Milk: Cattle	2%	Rapeseeds/canola seeds		
	14%	SE general	0.68	6%	Wheat	5%	Milk: Cattle	2%	Bovine: Muscle/meat		
	13%	IT toddler	0.66	13%	Wheat		FRUIT AND TREE NUTS				
	12%	GEMS/Food G11	0.59	7%	Wheat	3%	Milk: Cattle	0.5%	Swine: Muscle/meat		
	11%	DE women 14-50 yr	0.57	5%	Milk: Cattle	4%	Wheat	0.9%	Sugar beet roots		
	11%	NL general	0.56	4%	Wheat	3%	Milk: Cattle	2%	Rapeseeds/canola seeds		
	11%	DE general	0.55	5%	Milk: Cattle	4%	Wheat	0.8%	Sugar beet roots		
	10%	IE adult	0.52	5%	Wheat	3%	Other farmed animals: Muscle/meat	2%	Milk: Cattle		
	9%	FR infant	0.47	7%	Milk: Cattle	2%	Wheat	0.3%	Other farmed animals: Muscle/meat		
	9%	ES adult	0.43	5%	Wheat	2%	Milk: Cattle	0.7%	Other farmed animals: Muscle/meat		
	8%	IT adult	0.41	8%	Wheat		FRUIT AND TREE NUTS				
	8%	FR adult	0.41	4%	Wheat	2%	Milk: Cattle	0.5%	Other farmed animals: Muscle/meat		
	8%	PT general	0.39	8%	Wheat		FRUIT AND TREE NUTS				
	6%	UK vegetarian	0.28	4%	Wheat	1%	Milk: Cattle	0.1%	Eggs: Chicken		
	5%	DK adult	0.27	2%	Wheat	2%	Milk: Cattle	0.4%	Swine: Muscle/meat		
	5%	UK adult	0.27	3%	Wheat	1%	Milk: Cattle	0.3%	Bovine: Muscle/meat		
	5%	LT adult	0.23	2%	Wheat	2%	Milk: Cattle	0.4%	Swine: Muscle/meat		
	4%	IE child	0.20	2%	Wheat	1%	Milk: Cattle	0.1%	Swine: Muscle/meat		
	3%	FI 3 yr	0.15	2%	Wheat	0.6%	Rapeseeds/canola seeds	0.1%	Honey and other apiculture products		
	2%	FI 6 yr	0.12	2%	Wheat	0.4%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products		
	0.7%	FI adult	0.03	0.6%	Wheat	0.0%	Rapeseeds/canola seeds				
		Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
<p>Conclusion: The estimated long-term dietary intake (TMDI/IED/IEDI) was below the ADI. The long-term intake of residues of Acetamiprid is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.</p>											

The acute risk assessment was performed taking into account the applicable EU MRLs (Reg. (EU) 2019/88) for the intended crops, except for honey, where the new proposed MRL have been considered.

ADI	0.005 mg/kg bw per day
ARfD	0.005 mg/kg bw
IEDI (% ADI) according to EFSA PRIMo 3.1	43% (based on NL toddler) 9% (based on FR child)
IESTI (% ARfD) according to EFSA PRIMo3.1	29% wheat 11% rapeseeds Processed commodities 25% whet/milling (flour) 22% sugar beets (root)/sugar

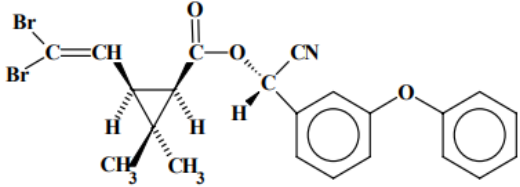
5% rapeseeds/oils																
Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment/children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRMO when the UK was a member of the European Union. The calculation is based on the large portion of the most critical consumer group.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	29%	Wheat	0.1 / 0.1	1.4	17%	Wheat	0.1 / 0.1	0.84	29%	Wheat	0.1 / 0.1	1.4	17%	Wheat	0.1 / 0.1	0.84
	11%	Rapeseeds/canola seeds	0.4 / 0.4	0.55	4%	Rapeseeds/canola seeds	0.4 / 0.4	0.21	11%	Rapeseeds/canola seeds	0.4 / 0.4	0.55	4%	Rapeseeds/canola seeds	0.4 / 0.4	0.21
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)								
Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI new):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	24%	Wheat / milling (flour)	0.1 / 0.1	1.2	9%	Wheat / bread/pizza	0.1 / 0.1	0.44	24%	Wheat / milling (flour)	0.1 / 0.1	1.2	24%	Wheat / milling (flour)	0.1 / 0.1	0.44
	22%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	9%	Sugar beets (root) / sugar	0.01 / 0.12	0.44	22%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	9%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
	11%	Wheat / milling (wholemeal)	0.1 / 0.1	0.55	8%	Wheat / pasta	0.1 / 0.1	0.38	11%	Wheat / milling (wholemeal)	0.1 / 0.1	0.55	8%	Wheat / pasta	0.1 / 0.1	0.38
	5%	Rapeseeds / oils	0.4 / 0.8	0.24	7%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35	5%	Rapeseeds / oils	0.4 / 0.8	0.24	7%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35
	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI
	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI

The proposed uses of Acetamiprid in CHR/I/ADEL 280 SC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Deltamethrin

General data on Deltamethrin are summarized in the table below (last updated 2002/10/17)

Table 7.3-1: General information on Deltamethrin

Active substance (ISO Common Name)	Deltamethrin
IUPAC	(S)- α -cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
Chemical structure	
Molecular formula	C ₂₂ H ₁₉ Br ₂ NO ₃
Molar mass	505.2
Chemical group	Pyrethroid, IRAC MoA group 3
Mode of action (if available)	- It prevents the transmission of nervous impulses in harmful organisms thereby disrupting their nervous system
Systemic	No
Company (ies)	Hoechst Schering AgrEvo GmbH, Aventis CropScience
Rapporteur Member State (RMS)	Austria
Approval status	Approved Date of (01/11/2003) Reg. (EU) No 540/2011
Restriction	Reg. (EU) No 540/2011 Only uses as insecticide may be authorised -must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures, -must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate. -should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels
Review Report	Deltamethrin 6504/VI/99-final 17/10/2002
Current MRL regulation	Reg. (EU) 2018/832

	Reg.(EU) 2024/1342
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	No
EFSA Journal: conclusion on article 12	Yes, EFSA Journal 2015;13(11):4309
Current MRL applications on intended uses	N/A – MRL already set

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
lettuce	High water content	stable for 8 months at $-15\pm 5^{\circ}\text{C}$	Grigor, 1990, Storage stability study for combined residues of tralomethrin, deltamethrin and trans-deltamethrin in lettuce in a freezer stability study.
Hops and beer	High water content	stable for 5.5 months at -20°C	Fuchsbichler, 1990, Hoe 032640 (Deltamethrin) Storage stability in hops and beer (storage interval 5 ½ months)
Ginned cotton seeds	High oil content	stable for at least 38 months at -12°C to -27°C	McKinney and Clayton, 1995a, Stability of Tralomethrin, cis-Deltamethrin and trans-Deltamethrin in Cottonseed Under Freezer Storage Conditions with alpha-R-Deltamethrin and Stability in Processed Commodities (Cottonseed Fractions)
crude cotton oil and soapstock	High oil content	stable for 24 months at -12°C to -27°C	
cotton hull	High oil content	stable for 13 months at -12°C to -27°C	
corn, rice, sorghum and wheat grain	High starch content	stable for at least 9 months at -23°C to -27°C	McKinney, F.R.; Crotts, D.G 1993b, Determination of cis-Deltamethrin, trans-Deltamethrin and alpha-R-Deltamethrin in Various Grain, Grain Fractions and Grain Dusts Under 20°C , 30°C , and Frozen Storage

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
			Conditions
Animal Products			
eggs	egg	stable for at least 13 months at -12°C to -27°C	McKinney, 1994c, Determination of Freezer Residue Stability for deltamethrin(Alpha-R, and Trans) and Tralomethrin in Poultry Tissue
fat	fat	stable for at least 12 months at -23°C to -27°C	
muscle	muscle	stable for at least 9 months at -23°C to -27°C	

Conclusion on stability of residues during storage

Under deep frozen conditions below -12°C to -27°C, there was no significant degradation (>30%) of deltamethrin in any of the fortified samples.

zRMS comments:

Stability of residues in plants according to EFSA Journal 2015;13(11):4309:

Plant products	Category	Commodity	T (°C)	Stability (months)
	High water content	Lettuce	-20	26
		Cabbage	-20	34
		Tomato	-20	24
	High oil content	Cotton seed	-12	30
	Dry/High starch	Cereals grain	-12	9
Studies cover also the stability of the isomers included in the residue definition. Result from the storage stability study on tomatoes (borderline between highwater and acidic commodity) are extrapolated to the acidic commodities. Sources: Sweden, 1998, 2002; FAO, 2002.				

Data are sufficient to cover the trials supporting intended GAPs of CHR/I/ADEL 280 SC.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

The time between extraction and analysis was always less than 24 hours.

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Not relevant

zRMS comments:

The stability of the analytes through the analytical procedures is adequately demonstrated by the procedural recoveries.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Apple	[¹⁴ C-dimethyl]- and [¹⁴ C-benzyl]-deltamethrin	Spray, F	0.06	2	28		Periasamy, R.; Kimmel, Ella C.; Toia, Robert F 1994a, Metabolism of [¹⁴ C-Acid]- and [¹⁴ C-Alcohol] Decis (Deltamethrin) in Apples
	Tomato	[¹⁴ C-gem dimethyl] and [¹⁴ C-benzyl] -deltamethrin	Spray, G	0.05	1	4, 14, 28		Merricks and North, 1985b Identification of the residues of ¹⁴ C-labelled deltamethrin, Decis, in the tomato plant.
			Syringe, G	0.0125	4	7, 14, 28		
Leafy vegetables Pulses/Oilseeds Studies I and II on cotton cover the metabolism in leafy vegetables. Study on cotton (I) performed in open field and in glasshouse. Study on cotton (II)investigated translocation. Sources: Sweden, 1998,	Cotton leaves (I)	[¹⁴ C-dibromovinyl]-, [¹⁴ C-benzyl]- and [¹⁴ C-cyano]-deltamethrin	applied topically, G and F	3-15 mg/kg per leaf	1	14, 42		Ruzo and Casida, 1979 Degradation of decamethrin on cotton plants
	Cotton plants (III)	[¹⁴ C-gem-dimethyl]- or [¹⁴ C-benzyl]-deltamethrin	Spray, F	0.224	2	4, 10, 28		O’Grodnick and Larson 1990 ¹⁴ C-Deltamethrin: Nature of the residue in cotton.
	Cotton plants	[¹⁴ C-gem-dimethyl]- or	Foliar	0.009 mg/plant	2	1, 3, 7		Larson 1991 ¹⁴ C-

2002; FAO, 2002	(II)	[¹⁴ C-benzyl]-deltamethrin	Soil	0.18 mg/plant				Deltamethrin: nature of the residue in cotton (Analytical phase – Supplements number 1 and 2)
			Hydroponic	6.7 mg/plant				
Cereals	Field corn	[¹⁴ C-dimethyl]- and [¹⁴ C-benzyl]-deltamethrin	Spray, G	0.110	2	0, 14, 42		Periasamy et al., 1994b Metabolism of [¹⁴ C-Acid]- and [¹⁴ C-Alcohol] Decis (Deltamethrin) in Field Corn

Summary of plant metabolism studies reported in the EU

The following studies showed that parent deltamethrin was the main metabolite and that the degradation was similar in these crops: Field studies at exaggerated GAP (apple, field corn, and tomato); Cotton leaves in glasshouse and in field. These studies are concluded to be representative for the crop categories fruits, cereals and oilseeds.

The major identified products of deltamethrin metabolism in plants are analogous to those in mammals but differ in the conjugating moieties involved. The proposed degradation pathway consists of isomerisation, hydrolysis, ester cleavage, reduction, oxidation and hydroxylation.

It is concluded that the submitted studies give sufficient information to propose a definition of the residue, in plants, as deltamethrin.

Conclusion on metabolism in primary crops

The metabolism of deltamethrin in primary crops following foliar treatment has been investigated in fruits and fruiting vegetables (apples and tomatoes), pulses and oilseeds (cotton seed and leaves) and cereals (corn). Deltamethrin was the predominant compound in all the crops tested accounting for up 77% total radioactive residue (TRR) (forage corn). In the studies analysing for the single isomers (apples, corn and cotton), the alpha-R-isomer and the trans-isomer accounted for up 34% TRR (apple) and for up to 19% TRR (apples), respectively. In all crops investigated, residues of metabolite 3-phenoxybenzylaldehyde (mPB aldehyde) were found but their levels were never relevant compared to parent and its isomers.

zRMS comments:

The metabolism of deltamethrin in primary crops belonging to the groups of fruits (apples and tomatoes), pulses and oilseeds (cotton seed) and cereals (maize) was investigated in the framework of the MRL review (EFSA, 2015). The metabolism studies after foliar and local treatment showed that the metabolic pathway is similar in all crop groups investigated. Deltamethrin was the main component of residues (up to 77% of the total radioactive residue (TRR)) with alpha-R-isomer and trans-isomer accounting for approximately 30–40% of the TRR.

For the intended uses on oilseed rape, wheat and sugar beet, the metabolic behaviour in primary crops is sufficiently addressed.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	lettuce	[¹⁴ C-benzyl]-deltamethrin	Spray, F	10 x 0.045	30, 120	Harvested at half nad full maturity		Erstfeld, Larson, and Lange, 1991 C-14 deltamethrin: Confined Accumulation In Rotational Crops 30 And 120 Day Experiment.
Root and tuber vegetables	carrots							
Cereals	barley							

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

With the exception of barley straw (~0.2 mg/kg at ≥2X), no significant residues (>0.01 mg/kg) were found in edible parts of succeeding crops.

Conclusion on metabolism in rotational crops

Following treatment of a bare soil at 10 × 0.45 kg a.s./ha, residues in rotational crops at harvest were generally found to be below 0.01 mg eq/kg, except in barley straw and foliage where residues amounted to 0.023 and 0.016 mg eq/kg, respectively. Consequently, considering the overdosing factor of the confined study (86N), no significant residues are expected in crops grown in rotation and a specific residue definition for rotational crops is not required.

zRMS comments:

Deltamethrin is proposed to be used on wheat, oilseed rape and sugar beet which can be grown in rotation with other crops. A rotational crop metabolism study is available and was assessed in the framework of the MRL review (EFSA Journal 2015;13(11):4309). EFSA concluded that the metabolism in rotational crops was comparable to that in primary crops.

For the intended uses, the metabolic behaviour in rotational crops is sufficiently addressed and no further information is required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Nature of the residues in processed commodities

EU data:

The mean distribution of radioactivity for each of the hydrolysis processes:

Process	Rate mg/ L	Deltamethrin % applied	3-phenoxy benzaldehyde % applied	(1R,3R)-3-(2,2- dibromovinyl)- 2,2- dimethyl- cyclopropanecarbox- ylic acid (Br2CA) % applied	Deltamethrin amide % applied	Unknown % applied
Pasteurisation 90°C, pH 4, 20 mins	0.1*	95.6	2.2	-	-	-
	1*	94	0.9	-	-	-
Baking 100°C, pH 5, 60 mins	0.1*	91.3	5.2	-	-	-
	1*	96.6	3.5	-	-	-
Sterilisation 120°C, pH 6, 20 mins	0.1*	21.3	74.9	-	2.9	-
	1*	29.8	59.1	-	3.4	-
	0.1†	23.8	-	47.0	5.1	12.6
	1†	42.5	-	39.3	-	6.7

*[¹⁴C] – Benzyl deltamethrin

†[¹⁴C] – Gemdimethyl deltamethrin

Conclusion on nature of residues in processed commodities

After pre-harvest applications, cooking and peeling of fruits and vegetables eliminated 15-66% of the residues. Roasting of coffee beans eliminated all residues. There was a concentration of residues when making ketchup from tomatoes and jam from fruits. No detectable residues were found in tea made from treated leaves or in beer made from treated hops.

After post-harvest applications more than 80% of the residues were eliminated when transforming wheat to flour or bread, and when polishing rice. In malt and beer made from treated barley, no residues were detected. Residues from treated maize were concentrated in the maize oil. Cooking pulses (>1h) eliminated 90% of the residues. Peeling potatoes eliminated all residues. Besides that, according to EU regulation 283/2013 studies for substances with a water solubility < 0,01 mg/L are not required. Solubility of Deltamethrin in water is 0.0002 mg/l according to deltamethrin DAR final list of endpoints.

zRMS comments:

The effect of processing on the nature of deltamethrin has been investigated in the framework of Directive 91/414/EEC (Sweden, 2002) and in the framework of the MRL review (EFSA Journal 2015;13(11):4309). It was concluded that deltamethrin is hydrolytically stable under conditions simulating pasteurisation and brewing, baking and boiling. Under sterilisation conditions, significant degradation of deltamethrin in two main metabolites was observed, which were considered during the peer review as well-known plant metabolites with no toxicological relevance, and therefore, this evidence base was accepted during the MRL review (EFSA Journal 2015;13(11):4309). In the MRL review, it was outlined that in the hydrolysis studies, residues were reported as deltamethrin however it was not clear whether the analytical method used analysed for the sum of all isomers.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3-6: Summary of the nature of residues in commodities of plant origin

Endpoints

Plant groups covered	Fruits and fruiting vegetable (Apple, Tomato) Leafy vegetables (Cotton leaves, Cotton plants) Cereals (Field corn) Pulses/oilseeds (cotton)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (carrots) Cereals (barley)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required (EU regulation 283/2013) stable under pasteurisation and baking/boiling /brewing conditions and not stable under sterilisation conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Not required (EU regulation 283/2013) Pasteurization: yes baking/brewing/boiling: yes Sterilisation: No
Plant residue definition for monitoring	Deltamethrin (tentative) EFSA Journal 2015;13(11):4309 Delthametrin (cis-delthametrin), Reg. (EU) 2024/1342
Plant residue definition for risk assessment	sum of deltamethrin ant its alpha-R isomer and trans-isomer (tentative) EFSA Journal 2015;13(11):4309
Conversion factor from enforcement to RA	1.25 EFSA Journal 2015;13(11):4309 : A reliable CF for risk assessment can be calculated only for radishes and asparagus. For all other crops, a tentative conversion factor of 1.25 for risk assessment is derived considering that,according to the RMS, results from 263 residue samples showed that the combined contribution of both the trans- and alpha R-isomers would not exceed 20% of the residue

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	¹⁴ C-gem-dimethyl or ¹⁴ C-	2	¹⁴ C-benzyl-1.64	3	Milk	twice a day	Struble C.B and Singh H, 1990, Metabolism of ¹⁴ C-benzyl-tralomethrin and ¹⁴ C-gem-dimethyl-
						Urine and faeces	twice a day	

		benzyl		¹⁴ C-gem-dimethyl-1,58 10		Tissues	at sacrifice	tralomethrin in lactating dairy cattle and storage stability of tralomethrin and deltamethrin in cow milk and tissues.
Laying poultry	Hens	¹⁴ C-gem-dimethyl or ¹⁴ C-benzyl	4	7.5 5	3	Eggs	daily	Akhtar et al., 1985e Metabolism, distribution and excretion of deltamethrin by Leghorn hens
						Excreta	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Deltamethrin was the predominant compound in all the crops tested accounting for up to 77% total radioactive residue (TRR) (forage corn). In the studies analysing for the single isomers (apples, corn and cotton), the alpha-R-isomer and the trans-isomer accounted for up to 34% TRR (apple) and for up to 19% TRR (apples), respectively. In all crops investigated, residues of metabolite 3-phenoxybenzylaldehyde (mPB aldehyde) were found but their levels were never relevant compared to parent and its isomers.

Conclusion on metabolism in livestock

The definition of the residue in the monograph, is confirmed.

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.3-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating cows
	Laying hens
Time needed to reach a plateau concentration	No information available for milk.
	2 days (eggs)
Animal residue definition for monitoring	Deltamethrin (tentative) EFSA Journal 2015;13(11):4309 Deltamethrin (cis-deltamethrin), Reg. (EU) 2024/1342
Animal residue definition for risk assessment	sum of deltamethrin and its alpha-R isomer and trans-isomer (tentative) EFSA Journal 2015;13(11):4309
Conversion factor	Data do not allow to derive CFs.
Metabolism in rat and ruminant similar	yes
Fat soluble residue	Yes (log Pow = 4.6)

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of CHR/I/ADEL 280 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Winther wheat	Kicińska J. 2018, ZBBZ-2017/05/DPL/1 It is not indicated whether trans- and alpha-R-deltamethrin is determined by this method, therefore the results are informative only. Results do not support the proposed use.	NEU	Grain: New Studies GAP, 1 application, BBCH 59-83, PHI 27-60, 5 g a.s./ha E: 5 x <0.003, 0.0019, 0.0026, 0.0046 RA: 5 x <0.003, 0.0019, 0.0026, 0.0046	0.003	0.0046	0.009	1	yes
			Straw: New Studies GAP, 1 application, BBCH 59-83, PHI 27-60, 5 g a.s./ha E: 0.0177, 0.247, 0.0362, 0.124, 0.02, 0.252, 0.0917, 0.101 RA: 0.0177, 0.247, 0.0362, 0.124, 0.02, 0.252, 0.0917, 0.101	0.096	0.252	-	-	-
Spring	Kicińska J. 2018,	NEU	Grain: New Studies GAP, 1 application, BBCH 75, PHI 27-31, 5	0.010	0.016	0.033	2	yes

Barley	ZBBZ- 2017/06/DPL/1 The study has not been evaluated and does not support the proposed use on wheat. According to the SANTE/2019/12752 Rev01, barley study results can be extrapolated to wheat before forming of the edible part. In case of cereals "before forming of the edible part" must be intended as before stage BBCH 51. Proposed in intended GAP, max BBCH for wheat and triticale is 75.		g a.s./ha E: 0.0096, 0.01, 0.0086, 0.016 RA: 0.0096, 0.01, 0.0086, 0.016 Straw: New Studies GAP, 1 application, BBCH 75, PHI 27-31, 5 g a.s./ha E: 0.15, 0.10, 0.052, 0.11 RA: 0.15, 0.10, 0.052, 0.11	0.105	0.15	-	-	-
Formulation SC								
Winter wheat	Peda, T., Głowiak, K., 2024, 23SGS35, Peda, T., Głowiak, K., 2024, 23SGS37, Peda, T., Głowiak, K., 2024, 23SGS38, Peda, T., Niewelt-Stasiak, S., 2024, 23SGS39	NEU	Grain: New studies GAP: 1 application, BBCH: 77-79, 4.8 g a.s./ha PHI: 25-35 E: 3x< 0.002, < 0.01 RA: 3x<0.002, <0.01 3 x <0.006, <0.03	<0.002	<0.01	0.02 0.01	0.1 1	Yes
		NEU	Straw: New studies GAP: 1 application, BBCH: 77-79, 4.8 g a.s./ha PHI: 25-35 E: 0.10, 0.15, 0.16, 0.46 RA: 0.10, 0.15, 0.16, 0.46	0.155	0.46	!	!	!

Oilseed rape	E. Thomas-Delille, Study code: C1179 C1180 C1181 C1182 C1183	NEU	Seeds: New Studies GAP, 1 application, BBCH 72, 5 g a.s./ha E: 5x <0.003 RA: 5x <0.003 5x < 0.009	<0.003	<0.003	<0.003	0.2	yes
Sugar beet	E. Thomas-Delille, Study code: C1147 C1148 C1149 C1150 C1151	N-EU	New studies GAP, 1 application, BBCH 37, 5 g as/ha: E: Roots: 5x <0.003 Leaves with top: 4x <0.003, 1x <0.01 1x 0.01 RA Roots: 5x <0.003 5 x <0.009 Leaves with top: 4x <0.003, 1x <0.01 4 x <0.009, 1 x 0.07 :	<0.003	<0.01 0.003	- 0.003	0.02	yes
Honey	Lefebvre, C., 2022, C1201, Lefebvre, C., 2022, C1202, Lefebvre, C., 2022, C1203, Lefebvre, C., 2022, C1204	EU	GAP: 1 x 0.05 kg as/ha, BBCH 63-65 E: 4x <0.003 RA: 4x <0.003 0.009	<0.003	<0.003	-	0.05	yes

* Source of EU MRL: Reg. (EU) 2018/832

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on Winter wheat, spring barley, oilseeds rape and sugar beets are considered acceptable, for both indoor and outdoor uses.

The uses are considered acceptable.

zRMS comments:

Deltamethrin

Wheat

EU GAP, EFSA Journal 2016;14(2):4385:

3 appl., interval 14 days, BBCH n.a., max appl. rate per treatment 7.5 g a.s./ha, PHI-30 days, EC formulation

Intended GAP: 1 appl., BBCH 37-75, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 4 adequate independent studies performed for the SC formulation. All of them are covered by stability studies for wheat grain. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no deltamethrin residues above LOQ in grain. Straw residue results were found in the range 0.1 mg/kg – 0.46 mg/kg (STMR – 0.155 mg/kg).

The data submitted show that no exceedance of the MRL (1 mg/kg, according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

The proposed uses on wheat and triticale are accepted.

Oilseed rape

EU GAP, EFSA Journal 2015;13(11):4309:

4 appl., interval 14 days, BBCH n.a., max appl. rate per treatment 6.25 g a.s./ha, PHI-45 days, EC formulation

Intended cGAP: 1 appl., BBCH 30-70, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 4 adequate independent studies performed for the SC formulation. All of them are covered by stability studies for wheat grain. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application. All studies showed no deltamethrin residues above LOQ in seeds.

The data submitted show that no exceedance of the MRL (0.2 mg/kg according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

The proposed uses of deltamethrin on oilseed rape are accepted.

Sugar beets

EU GAP, EFSA Journal 2015;13(11):4309:

3 appl., BBCH n.a., max appl. rate per treatment 10 g a.s./ha, PHI-3 days, EC formulation

Intended cGAP: 1 appl., BBCH 12-19, max appl. rate 4.8 g a.s./ha, SC formulation

The Applicant provided 5 adequate independent studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage of crop during application.

All studies showed no deltamethrin residues above LOD in roots. One sample of leaves with tops contained deltamethrin at a level of 0.01 mg/kg. No residues above LOD were found in the remaining samples of leaves.

The data submitted show that no exceedance of the MRL (0.02 mg/kg according to Reg. (EU) 2018/832 and 0.01 mg/kg for sugar beet roots in not yet applicable Reg. (EU) 2024/1342) will occur.

The proposed use of deltamethrin on sugar beets is accepted.

Honey

The Applicant provided 4 adequate studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage.

All studies showed no deltamethrin residues above LOD in honey.

Samples were analysed 15 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.

The data submitted show that no exceedance of the MRL (0.05 mg/kg for honey according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-10: Input values for the dietary burden calculation (considering the uses authorized within the zone and the uses under consideration, **Animal model 2017)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: Deltamethrin (cis-deltamethrin)				
Sugar beet, tops	0.003 0.01	STMR HR	N/A	
Rape, forage	0.003	STMR/ HR	N/A	
Triticale, forage	0.16 0.46	STMR HR	N/A	
Triticale, hay	0.45 1.33	0.16 (STMR) × 2.9 (PF) 0.46 (HR) × 2.9 (PF)	N/A	
Triticale, straw	0.16 0.46	STMR HR	N/A	
Wheat, forage	0.16 0.46	STMR HR	N/A	
Wheat, hay	0.54 1.61	0.16 (STMR) × 3.5 (PF) 0.46 (HR) × 3.5 (PF)	N/A	
Wheat, straw	0.16 0.46	STMR HR	N/A	
Triticale, grain	0.002	STMR	N/A	
Wheat, grain	0.002	STMR	N/A	
Sugar beet, dried pulp	0.05	0.003 (STMR) × 18 (PF)	N/A	

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet, ensiled pulp	0.01	0.003 (STMR) \times 3 (PF)	N/A	
Sugar beet, molasses	0.08	0.003 (STMR) \times 28 (PF)	N/A	
Canola, meal	0.01	0.003 (STMR) \times 2 (PF)	N/A	
Distiller's grain	0.01	0.002 (STMR) \times 3.3 (PF)	N/A	
Rape, meal	0.01	0.003 (STMR) \times 2 (PF)	N/A	
Wheat, gluten meal	0.004	0.003 (STMR) \times 1.8 (PF)	N/A	
Wheat, mill by-pdts	0.01	0.003 (STMR) \times 7 (PF)	N/A	

Table 7.3-10: Results of the dietary burden calculation

Animal burden calculation												Deltamethrin					
According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"																	
Maximum Intake	Cattle								Sheep								
	Beef				Dairy				Ram/Ewe				Lamb				
	500 kg		12 kg		650 kg		25 kg		75 kg		2.5 kg		40 kg		1.7 kg		
(mg/kg bw/d)	0.0092		mg/kg bw/d	%	0.0151		mg/kg bw/d	%	0.0254		mg/kg bw/d	%	0.0245		mg/kg bw/d	%	
Contributor 1	Wheat	forage	20		Wheat	forage	20		Wheat	forage	40		Wheat	forage	30		
Contributor 2	Beet, sugar	ensiled pulp	25		Beet, sugar	ensiled pulp	40		Beet, sugar	dried pulp	40		Beet, sugar	dried pulp	40		
Contributor 3	Triticale	grain	40		Triticale	grain	40		Triticale	grain	20		Triticale	grain	30		
Contributor 4																	
Median intake	0.0034		mg/kg bw/d		0.0057		mg/kg bw/d		0.0085		mg/kg bw/d		0.0090		mg/kg bw/d		
Maximum Intake	Swine								Intakes > 0.004 mg/kg bw/d are highlighted								
	Breeding				Finishing												
	260 kg		6 kg		100 kg		3 kg										
(mg/kg bw/d)	0.009		mg/kg bw/d	%	0.000		mg/kg bw/d	%									
Contributor 1	Wheat	forage	20		Beet, sugar	dried pulp	20										
Contributor 2	Beet, sugar	dried pulp	20		Wheat	grain	70										
Contributor 3	Triticale	grain	60														
Contributor 4																	
Median intake	0.003		mg/kg bw/d		0.000		mg/kg bw/d										
Maximum Intake	Poultry																
	Broiler				Layer				Turkey								
	1.7 kg		0.12 kg		1.9 kg		0.13 kg		7 kg		0.5 kg						
(mg/kg bw/d)	0.000		mg/kg bw/d	%	0.013		mg/kg bw/d	%	0.000		mg/kg bw/d	%					
Contributor 1	Wheat	milled byprod	20		Wheat	forage	10		Wheat	milled byprod	20						
Contributor 2	Wheat	grain	70		Wheat	milled byprod	20		Wheat	grain	50						
Contributor 3					Wheat	grain	70										
Contributor 4																	
Median intake	0.000		mg/kg bw		0.005		mg/kg bw		0.000		mg/kg bw						
Intakes expressed on the dry matter basis (mg/kg DM)																	
mg/kg DM	Cattle				Sheep				Swine								
	Beef	Dairy			Ram/Ewe	Lamb			Breeding	Finishing							
Maximum	0.3839	0.39			0.76	0.58			0.38	0.01							
Median	0.1399	0.15			0.25	0.21			0.14	0.01							
														Intake > 0.1 mg/kg DM in red characters			
Poultry																	
	Broiler	Layer		Turkey													
Maximum	0.00	0.19		0.00													
Median	0.00	0.07		0.00													

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

According to EFSA Journal 2015;13(11):4309 Livestock feeding studies on lactating cows dosed with deltamethrin at 0.052 and 0.26 mg/kg bw per day during 28 days and on laying hens dosed with a mixture of tralomethrin and deltamethrin (1:1) at 0.093, 0.275 and 0.927 mg deltamethrin/kg bw per day during 28 days were evaluated during the peer review (Sweden, 1998, 2002). According to the additional information received during the completeness check, the analytical method used in the livestock feeding studies analyse for the sum of isomers. However, since a detailed evaluation report is not available, EFSA could not verify this information and it was not possible to derive CFs for risk assessment

Residues from livestock feeding studies

Ruminants Closest feeding level ^(a) 0.26 mg/kg bw 2.4 N rate (beef) 2.6 N rate (dairy)	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)	CF^(d)
		Mean (mg/kg)	Highest (mg/kg)	STMR_{Mo} (mg/kg)^(b)	HR_{Mo} (mg/kg)^(c)		
	Muscle	<0.027	<0.027	0.02	0.02	0.02* ^(f) (tentative)	-
	Fat	0.202	0.266	0.08	0.11	0.15 ^(f) (tentative)	-
	Liver	<0.027	<0.027	0.02	0.02	0.02* ^(f) (tentative)	-
	Kidney	-	-	-	-	-	-
	Milk	0.026	n.a.	0.02	0.02	0.02* ^(f) (tentative)	-
Poultry Closest feeding level ^(a) 0.275 mg/kg bw 2.4 N rate	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)	CF^(d)
		Mean (mg/kg)	Highest (mg/kg)	STMR_{Mo} (mg/kg)^(b)	HR_{Mo} (mg/kg)^(c)		
	Muscle	<0.02	<0.02	0.02	0.02	0.02* ^(f) (tentative)	-
	Fat	0.140	0.258	0.04	0.08	0.08 ^(f) (tentative)	-
	Liver	<0.02	<0.02	0.02	0.02	0.02* ^(f) (tentative)	-
	Eggs	<0.015	0.018	0.02	0.02	0.02* ^(f) (tentative)	-
Pig^(e) Closest feeding level ^(a) 0.26 mg/kg bw 2.9 N rate	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)	CF^(d)
		Mean (mg/kg)	Highest (mg/kg)	STMR_{Mo} (mg/kg)^(b)	HR_{Mo} (mg/kg)^(c)		
	Muscle	<0.027	<0.027	0.02	0.02	0.02* ^(f) (tentative)	-
	Fat	0.202	0.266	0.06	0.09	0.09 ^(f) (tentative)	-
	Liver	<0.027	<0.027	0.02	0.02	0.02* ^(f) (tentative)	-
	Kidney	-	-	-	-	-	-

* Indicates that the MRL is proposed at the limit of quantification.

n.a. not applicable

(a): Closest feeding level and N dose rate related to the maximum dietary burden.

(b): Mean residue level according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(c): Highest residue level for tissues and eggs and mean residue level for milk, all according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(d): A conversion factor for risk assessment could not be derived in the absence of a feeding study investigating simultaneously residue definitions for enforcement and risk assessment.

(e): Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs.

(f): In the absence of adequate feeding studies, all MRL proposals for commodities of animal origin are considered tentative.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

zRMS comments:

No exceedance of the MRLs for animal commodities (Reg. (EU) 2018/832 is expected.

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3).

7.3.5.1 Available data for all crops under consideration

According to EFSA Journal 2015;13(11):4309 no new data were submitted in the framework of this application.

Table 7.3-11: Overview of the available processing studies

Processed commodity	Number of studies ^(a)	Processing Factor (PF)		CF _p ^(b)
		Individual values	Median PF	
Indicative processing factors (limited dataset and/or residues not analysed according to the proposed residue definitions)				
Potatoes, unpeeled and boiled	4	0.22; 0.27; 0.19; 0.34	0.26	1.25
Potatoes, fried	4	0.03; 0.03; 0.04; 0.04	0.04	1.25
Apples, juice	1	0.01	0.01	1.25
Apples, wet pomace	1	5.70	5.70	1.25
Strawberries, canned	1	0.65	0.65	1.25
Tomatoes, paste	1	0.40	0.40	1.25
Tomatoes, ketchup	1	1.00	1.00	1.25
Tomatoes, juice	1	1.00	1.00	1.25
Dry pulses, cooked	1	0.10	0.10	1.25
Sunflower seed, crude oil	1	10	10	1.25
Rape seed, crude oil	1	10	10	1.25
Cotton seed, crude oil	1	0.02	0.02	1.25
Olives, crude oil after warm press	1	1.60	1.60	1.25
Barley, beer	1	0.02	0.02	1.25
Maize, crude oil	1	20	20	1.25
Rice, polished	1	0.20	0.20	1.25

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)

(b): Tentative conversion factor for risk assessment in the processed commodity is the same as derived from the raw commodities.

7.3.5.2 Conclusion on processing studies

The effect of processing on the nature of deltamethrin was investigated in the framework of the peer review (Sweden, 2002). Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). Under simulated pasteurisation and brewing, baking and

boiling, deltamethrin is stable and only small quantities (0.9 to 5.2% of applied radioactivity) of the plant metabolite 3-phenoxybenzylaldehyde (mPB aldehyde) were detected. Following sterilisation process, deltamethrin represented 21-48% of the applied radioactivity (AR) and it was degraded mainly into two metabolites: mPB aldehyde (59-75% of the AR) and (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanecarboxylic acid (Br2CA) (39-47% of AR). During the peer review these two substances were considered well known plant metabolites with no toxicological relevance. Although their toxicological relevance may be reconsidered during the renewal of the approval of the active substance, the conclusions derived during the initial peer review were applied in the framework of this MRL review. It is also noted that in the hydrolysis studies, residues were always reported as deltamethrin and it is not clear if the analytical method used analysed for the sum of all isomers.

zRMS comments:

According to the EFSA Journal 2015;13(11):4309: Studies investigating the magnitude of residues in processed commodities of apples, tomatoes, pulses, sunflower seeds, rape seeds, cotton seed, olive, barley, maize, rice (Sweden, 1998, 2002), potatoes (EFSA, 2010) and strawberries (Italy, 2015) were reported. In these studies, residues were always reported as 'deltamethrin' and it is not clear if an analytical method covering all the isomers has been used. Consequently, no robust processing factors for enforcement and risk assessment could be derived. The processing factors should therefore be considered as indicative only.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.3-12: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Bare soil	0.1175	Leafy vegetables	Spinach	28 42	Krebs, Eickhoff, and Raquet, 1986 Deltamethrin - Bestimmung von Rueckstaenden in Gemuesekulturen nach Aufnahme aus kontaminiertem Boden
		Root and tuber vegetables	Carrot	106 133	
			Radishes	28 42	

Conclusion on rotational crops studies

The results of the confined rotational crop study is confirmed by a field rotational crop study analysing residues in spinach, carrots and radishes planted in soil treated once at 0.12 kg a.s./ha. Considering that deltamethrin was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the GAPs.

zRMS comments:

According to the EFSA Journal 2015;13(11):4309: The results of the confined rotational crop study is confirmed by a field rotational crop study analysing residues in spinach, carrots and radishes planted in soil treated once at 0.12 kg a.s./ha. Considering that deltamethrin was applied to a bare soil (interception of active substance by the plants is expected in practice), it can be concluded that residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the GAPs assessed in the present review.

Studies evaluated at EU level represent a much worse scenario, the dose proposed in the intended GAP is significantly lower. Residue levels in rotational commodities are not expected to exceed 0.01 mg/kg provided that deltamethrin is used according to the intended GAPs.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

Sugar beet, wheat and triticale have no melliferous capacity therefore magnitude of residues in honey are not necessary in accordance to SANTE/11956/2016 rev. 9 14 September 2018.

For spring winter oilseed rape application new magnitude of residues in honey were provided to support submission of the documentation of product CHR/I/ADEL 280 SC.

Risk from autumn application in winter oilseed rape is negligible, therefore no magnitude of residue studies are necessary to support this use.

Table 7.3-14: Summary of EU reported and new data supporting the intended uses of CHR/I/ADEL and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Honey	Lefebvre, C., 2022, C1201, Lefebvre, C., 2022, C1202, Lefebvre, C., 2022, C1203, Lefebvre, C., 2022, C1204	EU	GAP: 1 x 0.05 kg as/ha, BBCH 63-65 E: 4x <0.003 RA: 4x <0.003 0.009	N/A				

	Overall supporting data for cGAP	EU	RA: 4x <0.003	<0.003	<0.003	!	0.05*	Yes
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* Reg. (EU) 2018/832

The results of residues in honey do not exceed the currently established MRL value.

zRMS comments:

Sugar beet, wheat and triticale have no melliferous capacity therefore magnitude of residues in honey are not necessary. For oilseed rape application new magnitude of residues in honey were provided.

The Applicant provided 4 adequate studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage.

All studies showed no deltamethrin residues above LOD in honey.

Samples were analysed 15 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.

The data submitted show that no exceedance of the MRL (0.05 mg/kg for honey according to Reg. (EU) 2018/832 and not yet applicable Reg. (EU) 2024/1342) will occur.

Additional studies are not required,

7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: Residue definition: Deltamethrin (cis-deltamethrin)				
TMDI input values				
Rapeseeds/canola seeds	0.2	EU MRL Reg. (EU) 2018/832	0.2	EU MRL Reg. (EU) 2018/832
Wheat	1.0	EU MRL Reg. (EU) 2018/832	1.0	EU MRL Reg. (EU) 2018/832
Other cereals	1.0	EU MRL Reg. (EU) 2018/832	1.0	EU MRL Reg. (EU) 2018/832
Sugar beet roots	0.01	EU MRL Reg. (EU) 2018/832	0.01	EU MRL Reg. (EU) 2018/832
Rapeseed, oils	0.4	MRL × PF SANTE/11278/2021	0.4	MRL × PF SANTE/11278/2021

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat, bread (wholemeal)	1.0	MRL × PF SANTE/11278/2021	1.0	MRL × PF SANTE/11278/2021
Wheat, bread/ pizza	1.0	MRL × PF SANTE/11278/2021	1.0	MRL × PF SANTE/11278/2021
Wheat, pasta	1.0	MRL × PF SANTE/11278/2021	1.0	MRL × PF SANTE/11278/2021
Wheat, milling (wholemeal)- baking	1.0	MRL × PF SANTE/11278/2021	1.0	MRL × PF SANTE/11278/2021
Wheat, milling (flour)	1.0	MRL × PF SANTE/11278/2021	1.0	MRL × PF SANTE/11278/2021
Swine: Muscle/meat	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Swine: Fat tissue	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Swine: Liver	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Swine: Kidney	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Swine: Edible offals (other than liver and kidney)	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Swine: Other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Bovine: Muscle/meat	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Bovine: Fat tissue	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Bovine: Liver	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Bovine: Kidney	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Bovine: Edible offals (other than liver and kidney)	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Bovine: Other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Sheep: Muscle/meat	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Sheep: Fat tissue	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Sheep: Liver	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sheep: Kidney	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Sheep: Edible offals (other than liver and kidney)	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Sheep: other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Goat: Muscle/meat	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Goat: Fat tissue	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Goat: Liver	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Goat: Kidney	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Goat: Edible offals (other than liver and kidney)	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Goat: other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Equine: Muscle/meat	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Equine: Fat tissue	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Equine: Liver	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Equine: Kidney	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Equine: Edible offals (other than liver and kidney)	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Equine: Other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Poultry: Muscle/meat	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Poultry: Fat tissue	0.100	EU MRL SANTE/11278/2021	0.100	EU MRL SANTE/11278/2021
Poultry: Liver	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Poultry: Kidney	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Poultry: Edible offals (other than liver and kidney)	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry: Other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Other farmed animals: Muscle/meat	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Other farmed animals: Fat tissue	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Other farmed animals: Liver	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Other farmed animals: Kidney	0.030	EU MRL SANTE/11278/2021	0.030	EU MRL SANTE/11278/2021
Other farmed animals: Edible offals (other than liver and kidney)	0.500	EU MRL SANTE/11278/2021	0.500	EU MRL SANTE/11278/2021
Other farmed animals: Other products	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Milk: Cattle	0.050	EU MRL SANTE/11278/2021	0.050	EU MRL SANTE/11278/2021
Milk: Sheep	0.050	EU MRL SANTE/11278/2021	0.050	EU MRL SANTE/11278/2021
Milk: Goat	0.050	EU MRL SANTE/11278/2021	0.050	EU MRL SANTE/11278/2021
Milk: Horse	0.050	EU MRL SANTE/11278/2021	0.050	EU MRL SANTE/11278/2021
Milk: Others	0.050	EU MRL SANTE/11278/2021	0.050	EU MRL SANTE/11278/2021
Eggs: Chicken	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Eggs: Duck	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Eggs: Goose	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Eggs: Quail	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Eggs: Others	0.020	EU MRL SANTE/11278/2021	0.020	EU MRL SANTE/11278/2021
Honey and other apiculture products	0.05	EU MRL SANTE/11278/2021	0.05	EU MRL SANTE/11278/2021
IEDI/ESTI				
Rapeseeds/canola seeds	0.006	STMR	0.006	STMR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat	-	-	0.002	STMR
Other cereals	-	-	0.002	STMR
Sugar beet roots	-	-	0.002	STMR
Rapeseed, oils	-	-	0.002	STMR × PF
Wheat, bread (wholemeal)	-	-	0.002	STMR
Wheat, bread/ pizza	-	-	0.002	STMR
Wheat, pasta	-	-	0.002	STMR
Wheat, milling (wholemeal)-baking	-	-	0.002	STMR
Wheat, milling (flour)	-	-	0.002	STMR
Sugar beets (root), sugar	-	-	0.036	STMR
Honey and other apiculture products	-	-	<0.003	STMR

zRMS comments:

zRMS does not agree with the assessment made by the Applicant.

Input values used for the dietary exposure are summarized in Table below. The conversion factor of 1.25 was not applied for residues arising from the intended uses in wheat, sugar beet and oilseed rape. The samples from supporting residue trials were analysed according to the new residue definition for risk assessment: sum of deltamethrin ant its alpha-R isomer and trans-isomer.

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition: sum of deltamethrin ant its alpha-R isomer and trans-isomer				
Citrus fruits	0.01	STMRMo × CF (EFSA, 2015)	-	Acute risk assessment undertaken only with regard to crops under consideration
Tree nuts	0.03	STMRMo × CF (EFSA, 2015)	-	
Pome fruits	0.04	STMRMo × CF (EFSA, 2015)	-	
Apricot	0.03	STMRMo × CF	-	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2015)		
Cherries	0.04	STMR _{Mo} × CF (EFSA, 2015)	-	
Peaches	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Table and wine grapes	0.08	STMR _{Mo} × CF (EFSA, 2015)	-	
Strawberries	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Cane fruit	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Other small fruits and berries	0.10	STMR _{Mo} × CF (EFSA, 2015)	-	
Figs	0.06	STMR _{Mo} × CF (EFSA, 2015)	-	
Table olives	0.26	STMR _{Mo} × CF (EFSA, 2015)	-	
Kiwi	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Potatoes	0.02	STMR _{Mo} × CF (EFSA, 2015)	-	
Other root and tuber vegetables	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Garlic	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Onions	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Shallots	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Spring onions	0.07	STMR _{Mo} × CF (EFSA, 2015)	-	
Tomatoes	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Peppers	0.04	STMR _{Mo} × CF (EFSA, 2015)	-	
Aubergines (egg plants)	0.07	STMR _{Mo} × CF (EFSA, 2015)	-	
Cucurbits edible peel	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Cucurbits inedible peel	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	
Sweet corn	0.03	STMR _{Mo} × CF (EFSA, 2015)	-	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Flowering brassica	0.03	STMRMo × CF (EFSA, 2015)	-	
Brussels sprouts	0.01	STMRMo × CF (EFSA, 2015)	-	
Head cabbage	0.03	STMRMo × CF (EFSA, 2015)	-	
Chinese cabbage	0.02	STMRMo × CF (EFSA, 2015)	-	
Kale	0.05	STMRMo × CF (EFSA, 2018)	-	
Kohlrabi	0.01	STMRMo × CF (EFSA, 2015)	-	
Lamb's lettuce	0.43	STMRMo × CF (EFSA, 2015)	-	
Lettuce	0.19	STMRMo × CF (EFSA, 2015)	-	
Scarole	0.04	STMRMo × CF (EFSA, 2015)	-	
Cress	0.43	STMRMo × CF (EFSA, 2015)	-	
Land cress	0.43	STMRMo × CF (EFSA, 2015)	-	
Rocket rucola	0.43	STMRMo × CF (EFSA, 2015)	-	
Red mustard	0.43	STMRMo × CF (EFSA, 2015)	-	
Leaves and sprouts of Brassica spp	0.33	STMRMo × CF (EFSA, 2015)	-	
Spinach and similar leaves	0.43	STMRMo × CF (EFSA, 2015)	-	
Witloof	0.03	STMRMo × CF (EFSA, 2015)	-	
Herbs	0.43	STMRMo × CF (EFSA, 2015)	-	
Beans (fresh, with pods)	0.02	STMRMo × CF (EFSA, 2015)	-	
Beans (fresh, without pods)	0.03	STMRMo × CF (EFSA, 2015)	-	
Peas (fresh, with pods)	0.02	STMRMo × CF (EFSA, 2015)	-	
Peas (fresh, without pods)	0.02	STMRMo × CF (EFSA, 2015)	-	
Lentils (fresh)	0.02	STMRMo × CF	-	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2015)-		
Asparagus	0.02	STMRMo × CF (EFSA, 2015)	-	
Celery	0.08	STMRMo × CF (EFSA, 2017)	-	
Florence fennel	0.08	STMRMo × CF (EFSA, 2017)	-	
Rhubarb	0.08	STMRMo × CF (EFSA, 2017)	-	
Globe artichokes	0.07	STMRMo × CF (EFSA, 2015)	-	
Leek	0.07	STMRMo × CF (EFSA, 2015)	-	
Cultivated fungi	0.03	STMRMo × CF (EFSA, 2015)	-	
Pulses	0.25	STMRMo × CF (EFSA, 2015)	-	
Linseed	0.03	STMRMo × CF (EFSA, 2015)	-	
Poppy seed	0.06	STMRMo × CF (EFSA, 2015)	-	
Sesame seed	0.01	STMRMo × CF (EFSA, 2015)	-	
Sunflower seed	0.06	STMRMo × CF (EFSA, 2015)	-	
Rape seed	0.01	STMR-RA (LOQ)	0.01	HR-RA (LOQ)
Mustard seed	0.06	STMRMo × CF (EFSA, 2015)	-	Acute risk assessment undertaken only with regard to crops under consideration
Cotton seed	0.01	STMRMo × CF (EFSA, 2015)	-	
Pumpkin seed	0.01	STMRMo × CF (EFSA, 2015)	-	
Safflower	0.01	STMRMo × CF (EFSA, 2015)	-	
Borage	0.06	STMRMo × CF (EFSA, 2015)	-	
Gold of pleasure	0.06	STMRMo × CF (EFSA, 2015)	-	
Hempseed	0.06	STMRMo × CF (EFSA, 2015)	-	
Castor bean	0.06	STMRMo × CF (EFSA, 2015)	-	
Olives for oil production	0.26	STMRMo × CF	-	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2015)		
Barley grain	0.56	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Buckwheat grain	0.63	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Maize grain	0.56	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Millet grain	0.63	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Oats grain	0.63	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Rice grain	0.56	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Rye grain	0.56	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Sorghum grain	0.63	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	
Wheat grain	0.01	STMR-RA (LOQ)	0.01	HR-RA (LOQ)
Herbal infusions (dried flowers)	1.31	$STMR_{Mo} \times CF$ (EFSA, 2015)		Acute risk assessment undertaken only with regard to crops under consideration
Herbal infusions (dried leaves)	1.31	$STMR_{Mo} \times CF$ (EFSA, 2015)		
Herbal infusions (dried roots)	0.09	$STMR_{Mo} \times CF$ (EFSA, 2015)		
Spices (seeds)	0.06	EU MRL $\times CF$ (EFSA, 2015)		
Spices (fruits and berries)	1.31	$STMR_{Mo} \times CF$ (EFSA, 2015)		
Spices (roots and rhizome)	0.09	$STMR_{Mo} \times CF$ (EFSA, 2015)		
Spices (buds)	1.31	$STMR_{Mo} \times CF$ (EFSA, 2015)		
Spices (flower stigma)	1.31	$STMR_{Mo} \times CF$ (EFSA, 2015)		
Sugar beet (root)	0.01	STMR-RA (LOQ)	0.01	HR-RA (LOQ)
Chicory roots	0.01	$STMR_{Mo} \times CF$ (EFSA, 2015)	-	Acute risk assessment undertaken only with regard to crops under consideration
Swine meat	0.03	$0.8 \times STMR_{Mo}$ muscle+ $0.2 \times STMR_{Mo}$ fat (EFSA, 2015)	0.03	$0.8 \times STMR_{Mo}$ muscle+ $0.2 \times STMR_{Mo}$ fat (EFSA, 2015)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine fat (free of lean meat)	0.06	STMRMo (EFSA, 2015)	0.09	HRMo (EFSA 2015)
Swine liver	0.02	STMRMo (EFSA, 2015)	0.02	HRMo (EFSA 2015)
Swine kidney	0.03	EU MRL (EFSA 2015)	0.03	EU MRL (EFSA 2015)
Ruminant meat	0.03	$0.8 \times \text{STMRMo muscle} + 0.2 \times \text{STMRMo fat}$ (EFSA, 2015)	0.04	$0.8 \times \text{HRMo muscle} + 0.2 \times \text{HRMo fat}$ (EFSA, 2015)
Ruminant fat	0.08	STMRMo (EFSA, 2015)	0.11	HRMo (EFSA 2015)
Ruminant liver	0.02	STMRMo (EFSA, 2015)	0.02	HRMo (EFSA, 2015)
Ruminant kidney	0.03	EU MRL (EFSA 2015)	0.03	EU MRL (EFSA 2015)
Poultry meat	0.02	$0.9 \times \text{STMRMo muscle} + 0.1 \times \text{STMRMo fat}$ (EFSA, 2015)	0.03	$0.8 \times \text{HRMo muscle} + 0.2 \times \text{HRMo fat}$ (EFSA, 2015)
Poultry fat	0.04	STMRMo (EFSA, 2015)	0.08	HRMo (EFSA, 2015)
Poultry liver	0.02	STMRMo (EFSA, 2015)	0.02	HRMo (EFSA, 2015)
Ruminant milk	0.02	STMRMo (EFSA, 2015)	0.02	HRMo (EFSA, 2015)
Birds' eggs	0.02	STMRMo (EFSA, 2015)	0.02	HRMo (EFSA, 2015)

CF: Conversion factor (tentative). For all crops except asparagus, a tentative CF of 1.25 has been proposed for risk assessment (EFSA, 2015)

EFSA, 2015: EFSA Journal 2015;13(11):4309. Review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005.

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.


Table 7.3-14: Consumer risk assessment

Table 7.3-15: Consumer risk assessment for deltamethrin

TMDI (% ADI) according to EFSA PRIMo	81 % for wheat (based on IT toddler) 144% for wheat (based on children) 121% for wheat, milling (flour) (based on children)
IEDI (% ADI) according to EFSA PRIMo	0.2 % for wheat (based on IT toddler)

* include raw and processed commodities if both values are required for PRIMo

TMDI (% ADI) according to EFSA PRIMo	Not conducted, please refer to IEDI
IEDI (% ADI) according to EFSA PRIMo Rev. 3.1	78 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo Rev. 3.1	<p>Unprocessed commodities (based on children)</p> <p>Cattle milk: 25%</p> <p>Wheat: 1%</p> <p>Processed commodities (based on children)</p> <p>Sugar beets (root)/sugar: 11%</p> <p>Wheat/maize/(flour): 1%</p> <p>Rapeseeds/oils: 0.1%</p>

 EFSA European Food Safety Authority <small>EFSA PRIMO revision 3.1; 2021/01/06</small>		Deltamethrin				Input values	
LOQs (mg/kg) range from:		to:				Details - chronic risk assessment	
Toxicological reference values		ADI (mg/kg bw/day):		ARID (mg/kg bw):		Supplementary results - chronic risk assessment	
Source of ADI:		EC		Source of ARID:		EC	
Year of evaluation:		2002		Year of evaluation:		2002	
Details - acute risk assessment/children		Details - acute risk assessment/adults					
Comments:							
Normal mode							
Chronic risk assessment: JMPR methodology (IEDI/TMDI)							
No of diets exceeding the ADI:		---				Exposure resulting from commodities not in the LOQ (in % of ADI)	
Calculated exposure (% of ADI)	MS diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)
78%	NL toddler	7.76	39%	Maize/corn	12%	Milk: Cattle	4%
43%	DK child	4.30	31%	Rye	3%	Milk: Cattle	2%
27%	DE child	2.67	5%	Apples	4%	Rye	4%
27%	GEMS/Food G06	2.66	9%	Rice	7%	Maize/corn	1%
25%	GEMS/Food G10	2.45	7%	Rice	4%	Maize/corn	3%
24%	GEMS/Food G08	2.40	5%	Rye	3%	Maize/corn	2%
24%	UK infant	2.38	8%	Milk: Cattle	6%	Maize/corn	4%
21%	GEMS/Food G15	2.06	4%	Barley	4%	Maize/corn	2%
19%	NL child	1.91	5%	Milk: Cattle	2%	Apples	2%
18%	GEMS/Food G07	1.81	3%	Barley	2%	Rice	2%
18%	FR child 3-15 yr	1.79	5%	Milk: Cattle	2%	Rice	2%
18%	GEMS/Food G11	1.78	4%	Barley	2%	Rice	2%
17%	FR toddler 2-3 yr	1.70	3%	Milk: Cattle	2%	Apples	1%
16%	RO general	1.64	5%	Maize/corn	2%	Milk: Cattle	1%
16%	ES child	1.56	3%	Rice	2%	Milk: Cattle	2%
15%	IE adult	1.55	2%	Buckwheat and other pseudo-cereals	1%	Rice	1%
15%	PT general	1.54	4%	Rice	3%	Maize/corn	2%
15%	DE general	1.53	3%	Rye	3%	Barley	2%
15%	FI 3 yr	1.49	4%	Oat	4%	Rye	3%
14%	UK toddler	1.44	4%	Milk: Cattle	3%	Rice	2%
13%	DE women 14-50 yr	1.33	3%	Rye	2%	Milk: Cattle	1%
13%	LT adult	1.32	6%	Rye	1%	Buckwheat and other pseudo-cereals	1%
13%	SE general	1.30	2%	Milk: Cattle	2%	Rice	2%
12%	ES adult	1.21	3%	Barley	1%	Oat	1%
12%	FI 6 yr	1.16	3%	Rye	2%	Rice	2%
11%	NL general	1.08	2%	Milk: Cattle	2%	Barley	0.8%
8%	FR infant	0.84	3%	Milk: Cattle	1%	Squashes	0.7%
8%	DK adult	0.80	3%	Rye	1%	Milk: Cattle	0.8%
8%	FR adult	0.78	2%	Wine grapes	0.9%	Milk: Cattle	0.9%
8%	IT adult	0.77	4%	Rye	0.8%	Oat	0.7%
7%	UK vegetation	0.74	2%	Rice	0.9%	Beans	0.7%
6%	UK adult	0.64	2%	Rice	0.9%	Wine grapes	0.6%
6%	IT toddler	0.58	1%	Rice	0.7%	Wheat	0.6%
4%	IT adult	0.55	1%	Lettuces	0.5%	Lettuces	0.4%
3%	IE child	0.35	2%	Rice	0.7%	Milk: Cattle	0.1%
3%	PL general	0.31	0.8%	Apples	0.7%	Potatoes	0.3%
Conclusion:							
The estimated long-term dietary intake (TMDI/NEDI) was below the ADI.							
The long-term intake of residues of Deltamethrin is unlikely to present a public health concern.							
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.							

The acute risk assessment is based on the ARD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.																
The calculation is based on the large portion of the most critical consumer group.																
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (ESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (ESTI):				ESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.							
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	ESTI				ESTI				ESTI new							
	Highest % of ARID/ADI		Commodities		Highest % of ARID/ADI		Commodities		Highest % of ARID/ADI		Commodities					
	MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)					
	25%	Milk: Cattle	0.02 / 0.02	2.5	8%	Milk: Cattle	0.02 / 0.02	0.77	25%	Milk: Cattle	0.02 / 0.02	2.5	8%	Milk: Cattle	0.02 / 0.02	0.77
	5%	Poultry: Muscle/meat	0.01 / 0.03	0.51	4%	Milk: Goat	0.02 / 0.02	0.37	5%	Poultry: Muscle/meat	0.03 / 0.03	0.51	4%	Milk: Goat	0.02 / 0.02	0.37
	4%	Milk: Goat	0.02 / 0.02	0.48	3%	Poultry: Muscle	0.03 / 0.03	0.35	4%	Milk: Goat	0.02 / 0.02	0.48	3%	Poultry: Muscle	0.03 / 0.03	0.35
	4%	Swine: Muscle/meat	0.03 / 0.03	0.36	3%	Milk: Sheep	0.02 / 0.02	0.30	4%	Swine: Muscle/meat	0.03 / 0.03	0.36	3%	Milk: Sheep	0.02 / 0.02	0.30
	3%	Bovine: Muscle/meat	0.04 / 0.04	0.29	2%	Bovine: Muscle	0.04 / 0.04	0.23	3%	Bovine: Muscle/meat	0.04 / 0.04	0.29	2%	Bovine: Muscle	0.04 / 0.04	0.23
2%	Eggs: Chicken	0.02 / 0.02	0.25	2%	Equine: Muscle/meat	0.02 / 0.02	0.19	2%	Eggs: Chicken	0.02 / 0.02	0.25	2%	Equine: Muscle/meat	0.04 / 0.04	0.19	
2%	Equine: Muscle/meat	0.04 / 0.04	0.24	2%	Sheep: Muscle/meat	0.04 / 0.04	0.19	2%	Equine: Muscle/meat	0.04 / 0.04	0.24	2%	Sheep: Muscle/meat	0.04 / 0.04	0.19	
2%	Bovine: Fat tissue	0.11 / 0.11	0.11	2%	Swine: Fat tissue	0.09 / 0.09	0.16	2%	Bovine: Fat tissue	0.11 / 0.11	0.23	2%	Swine: Fat tissue	0.09 / 0.09	0.16	
2%	Sheep: Muscle/meat	0.04 / 0.04	0.22	2%	Sheep: Muscle/meat	0.03 / 0.03	0.15	2%	Sheep: Muscle/meat	0.04 / 0.04	0.22	2%	Sheep: Muscle/meat	0.03 / 0.03	0.15	
2%	Bovine: Liver	0.02 / 0.02	0.26	1%	Bovine: Fat tissue	0.11 / 0.11	0.11	2%	Bovine: Liver	0.02 / 0.02	0.16	1%	Bovine: Fat tissue	0.11 / 0.11	0.11	
2%	Swine: Fat tissue	0.09 / 0.09	0.15	0.9%	Poultry: Liver	0.02 / 0.02	0.09	2%	Swine: Fat tissue	0.09 / 0.09	0.15	0.9%	Poultry: Liver	0.02 / 0.02	0.09	
1%	Wheat	0.01 / 0.01	0.14	0.9%	Eggs: Chicken	0.02 / 0.02	0.09	1%	Wheat	0.01 / 0.01	0.14	0.9%	Eggs: Chicken	0.02 / 0.02	0.09	
1%	Bovine: Kidney	0.03 / 0.03	0.11	0.8%	Wheat	0.01 / 0.01	0.08	1%	Bovine: Kidney	0.03 / 0.03	0.11	0.8%	Wheat	0.01 / 0.01	0.08	
0.7%	Milk: Sheep	0.02 / 0.02	0.07	0.8%	Bovine: Liver	0.02 / 0.02	0.08	0.7%	Milk: Sheep	0.02 / 0.02	0.07	0.8%	Bovine: Liver	0.02 / 0.02	0.08	
0.4%	Swine: Kidney	0.03 / 0.03	0.04	0.7%	Swine: Kidney	0.03 / 0.03	0.07	0.4%	Swine: Kidney	0.03 / 0.03	0.04	0.7%	Swine: Kidney	0.03 / 0.03	0.07	
Expand/collapse list																
Total number of commodities exceeding the ARID/ADI in children and adult diets (ESTI calculation)																
Total number of commodities found exceeding the ARID/ADI in children and adult diets (ESTI new calculation)																
Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (ESTI):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (ESTI):				Results for children No. of processed commodities for which ARID/ADI is exceeded (ESTI new):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (ESTI new):			
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	ESTI				ESTI				ESTI new				ESTI new			
	Highest % of ARID/ADI		Processed commodities		Highest % of ARID/ADI		Processed commodities		Highest % of ARID/ADI		Processed commodities		Highest % of ARID/ADI		Processed commodities	
	MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	11%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	4%	Sugar beets (root) / sugar	0.01 / 0.12	0.04	11%	Sugar beets (root) / sugar	0.01 / 0.12	0.04	4%	Sugar beets (root) / sugar	0.01 / 0.12	0.04
	1%	Wheat / milling (flour)	0.01 / 0.01	0.12	0.4%	Wheat / bread/pasta	0.01 / 0.01	0.04	1%	Wheat / milling (flour)	0.01 / 0.01	0.12	0.4%	Wheat / bread/pasta	0.01 / 0.01	0.04
	0.6%	Wheat / milling (wholemeal)	0.01 / 0.01	0.06	0.4%	Wheat / pasta	0.01 / 0.01	0.04	0.6%	Wheat / milling (wholemeal)	0.01 / 0.01	0.06	0.4%	Wheat / pasta	0.01 / 0.01	0.04
	0.1%	Rapeseeds / oils	0.01 / 0.02	0.01	0.3%	Wheat / bread (wholemeal)	0.01 / 0.01	0.03	0.06%	Rapeseeds / oils	0.01 / 0.02	0.01	0.3%	Wheat / bread (wholemeal)	0.01 / 0.01	0.03
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#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	
#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	
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#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	
#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	
#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	#LCZBAI	
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7.5 References

EFSA Journal 2015;13(11):4309
EFSA Journal 2011;9(7):2328
EFSA Journal 2016;14(11):4610

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1	Turnbull, G.	2021	Completion of Analysis of Samples Generated in Study Number ACI19-002 Study No.: FR/000938-10 Fera Science Ltd., York, United Kingdom GLP Unpublished	N	Chemiroi
KCA 6.1	Niewelt, S.	2021	Acetamiprid in cereal grain - stability study DPL/01/2021 SGS Polska Sp. z o. o. GLP Unpublished	N	Chemiroi
KCA 6.1	Faessel, V.	2022	Frozen Storage Stability of Residues of Acetamiprid in honey. Study No.: C1310 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCP 6.3	Corinne Ertus	2018	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Poland in 2018 B8177 ANADIAG 16, rue Ampère 67500 HAGUENAU France GLP Unpublished	N	Chemiroi
KCP 6.3	Corinne Ertus	2018	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Northern France in 2018 B8183	N	Chemiroi

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			ANADIAG 16, rue Ampère 67500 HAGUENAU France GLP Unpublished		
KCP 6.3	Corinne Ertus	2018	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Northern France in 2018 B8185 ANADIAG 16, rue Ampère 67500 HAGUENAU France GLP Unpublished	N	Chemiroil
KCP 6.3	Corinne Ertus	2019	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Czech Republic in 2019 Study No. B9219 Anadiag, France GLP Unpublished	N	Chemiroil
KCP 6.3	Tomasz Peda, Monika Jędrusik	2021	Magnitude of the residue of acetamiprid in Winter wheat (Raw agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one decline curve trial in Poland – 2020 20SGS12 SGS Poland Sp. z o. o. ul. Jana Kazimierza 3, 01-248 Warszawa Polska GLP Unpublished	N	Chemiroil
KCP 6.3	Tomasz Peda, Monika Jędrusik	2021	Magnitude of the residue of acetamiprid in Winter wheat (Raw agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one decline curve trial in Germany– 2020 20SGS13 SGS Poland Sp. z o. o. ul. Jana Kazimierza 3, 01-248 Warszawa Polska GLP Unpublished	N	Chemiroil
KCP 6.3	Tomasz Peda, Grzegorz Paszek	2021	Magnitude of the residue of acetamiprid in Sugar beet (Raw agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one semi decline curve trial in Poland–	N	Chemiroil

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			2020 20SGS29 SGS Poland Sp. z o. o. ul. Jana Kazimierza 3, 01-248 Warszawa Polska GLP Unpublished		
KCP 6.3	Tomasz Peda, Monika Jędrusik	2021	Magnitude of the residue of acetamiprid in Winter wheat (Raw agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one harvest trial in Hungary– 2020 20SGS15 SGS Poland Sp. z o. o. ul. Jana Kazimierza 3, 01-248 Warszawa Polska GLP Unpublished	N	Chemrol
KCP 6.3	Tomasz Peda, Grzegorz Paszek	2021	Magnitude of the residue of acetamiprid in Sugar beet (Raw agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one semi decline curve trial in Poland– 2020 20SGS30 SGS Poland Sp. z o. o. ul. Jana Kazimierza 3, 01-248 Warszawa Polska GLP Unpublished	N	Chemrol
KCP 6.3	Grzegorz Paszek	2018	Determination of residues of Acetamiprid in Oilseed Rape (OSR), following foliar application of APIS 200 SE under field condition Northern France 2018 DPL/68/2018 SGS Polska Sp. z o. o. Ul. Cieszyńska 52A, 43-200 Pszczyna GLP Unpublished	N	Chemrol
KCP 6.3	Grzegorz Paszek	2018	Determination of residues of Acetamiprid in Oilseed Rape (OSR), following foliar application of APIS 200 SE Poland 2018 DPL/67/2018 SGS Polska Sp. z o. o. Ul. Cieszyńska 52A, 43-200 Pszczyna	N	Chemrol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 6.3	Grzegorz Paszek	2018	Determination of residues of Acetamiprid in Oilseed Rape (OSR), following foliar application of APIS 200 SE under field condition Northern France 2018 DPL/70/2018 SGS Polska Sp. z o. o. Ul. Cieszyńska 52A, 43-200 Pszczyna GLP Unpublished	N	Chemiroł
KCP 6.3	Grzegorz Paszek	2020	Final REPORT Determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Czech Republic and Germany in 2019 Study Plan No.: DPL/131/2019 SGS Polska Sp. z o.o. , ul cieszyńska 52A, 43-200 Pszczyna GLP Unpublished	N	Chemiroł.
KCA 6.3	Joanna Kicińska	2018	DETERMINATION OF RESIDUES OF DELTAMETHRIN IN WINTER WHEAT APPLIED AS “DELCAPS 050 CS” AND “DELTAMETHRIN 100 SC” IN NORTHERN EUROPE IN 2017 ZBBZ-2017/05/DPL/1 Food Safety Laboratory Research Institute of Horticulture 18 Pomologiczna Street, 96-100 Skierniewice POLAND GLP Unpublished	N	Chemiroł
KCA 6.3	Corinne Ertus	2017	Generation of Field Specimens for the determination of Deltamethrin residues in Winter Wheat Following Foliar application with DELCAPS 050 CS and Deltamethrin 100 SC under field conditions in Northern Europe in 2017 B7143 ANADIAG 16 rue Ampere 67500 HAGUENAU France GLP Unpublished	N	Chemiroł
KCA 6.3	Corinne Ertus	2017	Generation of Field Specimens for the determination of Deltamethrin residues in Spring Barley Following	N	Chemiroł

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Foliar application with Deltamethrin 100 SC under field conditions in Northern Europe in 2017 B7144 ANADIAG 16 rue Ampere 67500 HAGUENAU France GLP Unpublished		
KCA 6.3	Joanna Kicińska	2018	DETERMINATION OF RESIDUES OF DELTAMETHRIN IN SPRING BARLEY APPLIED AS “DELTAMETHRIN 100 SC” IN NORTHERN EUROPE IN 2017 ZBBZ-2017/06/DPL/1 Food Safety Laboratory Research Institute of Horticulture 18 Pomologiczna Street, 96-100 Skierniewice POLAND GLP Unpublished	N	Chemrol
KCA 6.3	Agnes Perny	2017	Determination of Deltamethrin Residues in Oilseed rape Following Foliar application with DelCaps under Field Conditions in Northern Europe in 2017 B7022 ANADIAG 16, rue Ampère 67500 HAGUENAU France GLP Unpublished	N	Chemrol
KCA 6.3	Agnes Perny	2018	Validation of the analytical Method for the Analysis of Deltamethrin in Oilseed rape seeds B7023 ANADIAG 16, rue Ampère 67500 HAGUENAU France GLP Unpublished	N	Chemrol
KCP 6.3	A. Augustynek	2017	Final Report Determination of residues of acetamiprid in oilseed rape Study No.: DPL/03/2017 SGS Polska Sp. z o.o. , ul cieszyńska 52A, 43-200 Pszczyna GLP Unpublished	N	Chemrol
KCP 6.3	K. Wanczyk	2022	Magnitude of the residue of Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ACE 200 SE – one single harvest trial in Northern France – 2021	N	Chemrol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study No.: 21SGS27 SGS Polska Sp. z o.o., ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished		
KCP 6.3	K. Wanczyk	2022	Magnitude of the residue of Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ACE 200 SE – one single harvest trial in Germany – 2021 Study No.: 21SGS26 SGS Polska Sp. z o.o., ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	K. Wanczyk	2021	Magnitude of the residue of Acetamiprid in winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with adjuvant Asystent+ – one harvest study in Hungary – 2021 Study No.: 21SGS33 SGS Polska Sp. z o.o., ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	K. Wanczyk	2022	Magnitude of the residue of Acetamiprid in winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with adjuvant Asystent+ – one semi decline curve study in Poland – 2021 Study No.: 21SGS32 SGS Polska Sp. z o.o., ul. Jana Kazimierza 3, 01-248 Warszawa, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	E. Thomas-Delille	2021	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1179 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiroł

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3	E. Thomas-Delille	2021	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1180 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiorol
KCP 6.3	E. Thomas-Delille	2021	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1181 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiorol
KCP 6.3	E. Thomas-Delille	2021	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1182 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiorol
KCP 6.3	E. Thomas-Delille	2021	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1183 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiorol
KCP 6.3	E. Thomas-Delille	2022	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021	N	Chemiorol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			C1147 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished		
KCP 6.3	E. Thomas-Delille	2022	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1148 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiroi
KCP 6.3	E. Thomas-Delille	2022	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1149 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiroi
KCP 6.3	E. Thomas-Delille	2022	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C1150 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiroi
KCP 6.3	E. Thomas-Delille	2022	Determination of Deltamethrin and its alpha-Risomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021 C11 51 ANADIAG, 16, rue Ampère, 67500 HAGUENAU, France GLP Unpublished	N	Chemiroi
KCP 6.3	Peda, T., Głowiak, K.	2024	Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter	N	Chemiroi

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC- one decline curve study trial in Poland – 2023 Study No.: 23SGS35 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished		
KCP 6.3	Peda, T., Głowiak, K.	2024	Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC- one harvest study trial in Northern France - 2023 Study No.: 23SGS37 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	Peda, T., Głowiak, K.	2024	Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC- one decline curve study trial in Germany - 2023 Study No.: 23SGS38 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	Peda, T., Niewelt-Stasiak, S.	2024	Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC- one harvest study trial in Hungary - 2023 Study No.: 23SGS39 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.3	Peda, T., Głowiak, K.	2024	Magnitude of residue of sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one decline curve study trial in Poland – 2023 Study No.: 23SGS40 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	Peda, T., Głowiak, K.	2024	Magnitude of residue of sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one harvest study trial in Northern France - 2023 Study No.: 23SGS42 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	Peda, T., Niewelt-Stasiak, S.	2024	Magnitude of residue of sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one harvest study trial in Germany - 2023 Study No.: 23SGS43 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCP 6.3	Peda, T., Niewelt-Stasiak, S.	2024	Magnitude of residue of sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one decline curve study trial in Hungary - 2023 Study No.: 23SGS44 SGS Polska Sp. z o.o., Warsaw, Poland GLP Unpublished	N	Chemiroł
KCA 6.6.1	Philip Rooney	2019	[¹⁴ C] IM 1 5: Metabolism in Rotational Crops FR/000939	N	Chemiroł

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Fera Science Limited Centre for Chemical Safety & Stewardship Sand Hutton York YO41 1LZ UK GLP Unpublished		
KCA 6.6.2	Gordon Turnbull	2021	Completion of Analysis of Samples Generated in Study Number ACI19-002 FR/000938-10 Fera Science Limited Centre for Chemical Safety & Stewardship Sand Hutton York YO41 1LZ UK GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2022	Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Northern Europe in 2020 Study No.: C0280 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2021	Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Southern Europe in 2020 Study No.: C0281 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2022	Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Southern Europe in 2021 Study No.: C1063 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2022	Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Northern Europe in 2021 Study No.: C1064 Anadiag, Haguenau, France	N	Chemiroi

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.10	Lefebvre, C.	2022	Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamehtrine formulation (CHR/I/DEL 100 SE) under semi field conditions in Northern Europe in 2021 Study No.: C1201 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2022	Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamehtrine formulation (CHR/I/DEL 100 SE) under semi field conditions in Northern Europe in 2021 Study No.: C1202 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2022	Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamehtrine formulation (CHR/I/DEL 100 SE) under semi field conditions in Southern Europe in 2021 Study No.: C1203 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi
KCA 6.10	Lefebvre, C.	2022	Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamehtrine formulation (CHR/I/DEL 100 SE) under semi field conditions in Southern Europe in 2021 Study No.: C1204 Anadiag, Haguenau, France GLP Unpublished	N	Chemiroi

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Goller G.	1999	Stability Study of NI-25 (Acetamiprid) in apple and tomato samples after storage in freezer at or below -18 °C - Fortification experiments with active ingredient Nippon-Soda Document No. RD-00340 A.D.M.E. – Bioanalyses, France, Report No. RPA/NI-25/97051, 97- 75 GLP, Not published	N	Nippon Soda
KCA 6.1	Gieseke, L.D.	1999	NI-25 (acetamiprid): Freezer storage stability of acetamiprid residues in various raw agricultural commodities and processing fractions (plant matrices). Report No. 10201, Document No. RD-00270 Horizon Laboratories, Inc GLP, not published	N	Nippon Soda
KCA 6.1	Jean-Baptiste C	2009	Frozen Storage Stability of Residues of Acetamiprid in Fodder Pea. Anadiag Laboratories. Report No. A7125, Document No. RD-01936. GLP, not published	N	Nippon Soda
KCA 6.1	Netzband, D. J	2003	Stability study of Acetamiprid in potatoes during frozen storage, USA, 2002 in freezer at or below -18°C 02Y535566, RD-00243; Doc No. 645-002, Test facility: Bayer CropScience, Residue Chemistry Department, Research Triangle Park, North Carolina, USA GLP, self-certified	N	Nippon Soda
KCA 6.2.1	Saito, H.	1997	NI-25 [Pyridine-2,6- ¹⁴ C] - Nature of the Residue in Eggplants Generated by:Nisso Chemical Analysis Service Co, Ltd Report/file:NCAS N°-2- 92 Amended Report N° EC-391-3 Source: Nippon Soda Date:Novembert 17, 1997 GLP, GEP : Yes Not published	N	Nippon Soda
KCA 6.2.1	Saito, H.	1997	NI-25 [Pyridine-2,6- ¹⁴ C] - Nature of the Residue in Apples Generated by:Nisso Chemical Analysis Service Co, Ltd Report/file:NCAS N°:2- 98 Amended Report-742-1 Source : Nippon Soda GLP, GEP : Yes Date : November 10, 1997 Not published	N	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1	Saito, H.	1997	NI-25 [Pyridine-2,6- ¹⁴ C] - Nature of the Residue in Cabbage plants Generated by:Nisso Chemical Analysis Service Co, Ltd Report/file:NCAS N°:2- 111 Amended Report EC-743-1 Source: Nippon Soda Date: November 10, 1997 GLP, GEP : Yes Not published	N	Nippon Soda
KCA 6.2.1	Kawai,T.	1995	Metabolism of ¹⁴ C-Acetamiprid (CN label) in Cabbages plants Generated by:Nisso Chemical Analysis Service Co, Ltd Report/file:NCAS N°:2- 137 NG Amended Report EC-617-1 Source: Nippon Soda GLP, GEP : Yes Date:October 23, 1997 Not published	N	Nippon Soda
KCA 6.2.1 KCA 6.5.1	McMillan-Staff, S.L., Austin, D.J. and Lingwood, A.	1997	[¹⁴ C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. Generated by: Rhône-Poulenc Agriculture Ltd Report/file:RPAL Study 13442 S Source: Nippon Soda Date: October 09, 1997 Not published	N	Nippon Soda
KCA 6.2.1	Miller N.	1999	Foliarly applied ¹⁴ C-acetamiprid: Metabolic fate and distribution in cotton (Gossypium hirsutum). Rhone-Poulenc Ag Company. Report No. EC-97-367, Document No. RD-00741 GLP, not published	N	Nippon Soda
KCA 6.2.2-6.2.5	-	1997	¹⁴ C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats. Source: Nippon Soda GLP, GEP : Yes Date: May 23, 1997 Not published	Y	Nippon Soda
KCA 6.2.2-6.2.5	-	1997	¹⁴ C-NI-25 (Acetamiprid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Laying Hens Source: Nippon Soda GLP. GEP : Yes Date: July 3, 1997 Not published	Y	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Grigor	1990	Storage stability study for combined residues of tralomethrin, deltamethrin and trans-deltamethrin in lettuce in a freezer stability study. Report No. A753531 (80401) ChemAlysis Inc., Washington, MD	N	Aventis
KCA 6.1	Fuchsbichler, G.	1990	Hoe 032640 (Deltamethrin) Storage stability in hops and beer (storage interval 5 ½ months) Generated by: Bayerische Hauptversuchsanstalt für Landwirtschaft der Technischen Universität München, Weihenstephan, 8050 Freising 1, Germany Company file No: HVA489 GLP, Unpublished	N	Aventis
KCA 6.1	McKinney and Clayton	1995a	Stability of Tralomethrin, cis-Deltamethrin and trans-Deltamethrin in Cottonseed Under Freezer Storage Conditions with alpha-R-Deltamethrin and Stability in Processed Commodities (Cottonseed Fractions) Generated by: EN-CAS Analytical Laboratories, 2359 Farrington Point Drive, Winston-Salem, NC 27107, USA Company file No: 890011 GLP, Unpublished	N	AgrEvo
KCA 6.1	McKinney, F.R.; Crotts, D.G	1993b	Determination of cis-Deltamethrin, trans-Deltamethrin and alpha-R-Deltamethrin in Various Grain, Grain Fractions and Grain Dusts Under 20°C, 30°C, and Frozen Storage Conditions Generated by: EN-CAS Analytical Laboratories, 2359 Farrington Drive, Winston-Salem, NC27107, USA Company file No: 910009 GLP, Unpublished	N	AgrEvo
KCA 6.1	McKinney	1994c	Determination of Freezer Residue Stability for deltamethrin(Alpha-R, and Trans) and Tralomethrin in Poultry Tissue Generated by: EN-CAS Analytical Laboratories, 2359 Farrington Point Drive, Winston-Salem, NC 27107, USA Company file No: 9300121 GLP, Unpublished	N	AgrEvo
KCA 6.2.1	Periasamy, R.; Kimmel, Ella C.; Toia, Robert F	1994a	Metabolism of [¹⁴ C-Acid]- and [¹⁴ C-Alcohol] Decis (Deltamethrin) in Apples Generated by: PTRL West, Inc. 4123-B Lakeside Drive, Richmond, CA 94806 USA Company file No: US305W1 GLP, Unpublished	N	AgrEvo
KCA 6.2.1	Merricks and North	1985b	Identification of the residues of ¹⁴ C-labelled deltamethrin, Decis, in the tomato plant. Generated by: Agrisearch Incorporated, 13456 Old Annapolis Road, MT. AIRY, Maryland 21771 USA Borrison Laboratories, Inc. 5050 Beach Place, Temple Hills Maryland 20748 USA for the analytics. Company file No: US4620	N	AgrEvo

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP, Unpublished		
KCA 6.2.1	Ruzo and Casida,	1979	Degradation of decamethrin on cotton plants Generated by: Pesticide Chemistry and Toxicology Laboratory, Department of Entomological Sciences, University of California, Berkeley, California 94720 J. Agric. Food Chem., Vol.27, No. 3, 1979, p. 572 - 575 Company file No: US572P Non-GLP, Published	N	AgrEvo
KCA 6.2.1	O'Grodnick and Larson	1990	¹⁴ C-Deltamethrin: Nature of the residue in cotton. Report No. A71094 Hoechst-Roussel Agri-Vet Company Mississippi Research Farm, Arcola, MS Hazelton Laboratories America Madison Wisconsin GLP, Unpublished	N	AgrEvo
KCA 6.2.1	Larson	1991	¹⁴ C-Deltamethrin: nature of the residue in cotton (Analytical phase – Supplements number 1 and 2) Report No. A71095 Hazelton Laboratories America, Madison, Wisconsin GLP, Unpublished	N	AgrEvo
KCA 6.2.1	Periasamy et al.	1994b	Metabolism of [¹⁴ C-Acid]- and [¹⁴ C-Alcohol] Decis (Deltamethrin) in Field Corn Generated by: PTRL West, Inc. 4123-B Lakeside Drive, Richmond, CA 94806 USA Company file No: US306W1 GLP, Unpublished	N	AgrEvo
KCA 6.6.1	Erstfeld, Larson, and Lange,	1991	C-14 deltamethrin: Confined Accumulation In Rotational Crops 30 And 120 Day Experiment Generated by: Pan-Agricultural Laboratories, Inc., California, USA, Hazleton Laboratories, Inc., Wisconsin, USA Company file No: US87116 GLP, Unpublished	N	AgrEvo
KCA 6.2.2-6.2.5	xxxxxxx	1990	Metabolism of ¹⁴ C-benzyl-tralomethrin and ¹⁴ C-gem-dimethyl-tralomethrin in lactating dairy cattle and storage stability of tralomethrin and deltamethrin in cow milk and tissues. Report No. A70045 (Project no. HLA 6187-113 and HR-01-88) xxxxxxxxxxxxxx	Y	Aventis
KCA 6.2.2-6.2.5	xxxxxxx	1985e	Metabolism, distribution and excretion of deltamethrin by Leghorn hens xxxxxxxxxxxxxxxxxxxxxxxxxx	Y	AgrEvo

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			xxxxxxxxxxxx Non-GLP, Published		
KCA 6.2.2-6.2.5	xxxxxxx	1988	Feeding study of a mixture of tralomethrin and deltamethrin in dairy cows and magnitude of the combined residues of tralomethrin, deltamethrin and trans-deltamethrin in milk and tissues of dairy cattle Report includes Trial Nos.: HRAV Proj. #87-0123 HRAV Project No. 87-0123 GLP	Y	Aventis
KCA 6.2.2-6.2.5	xxxxxxxxx	1992	Deltamethrin residues in milk and tissues of lactating dairy cows A70892 Non GLP	Y	AgrEvo
KCA 6.2.2-6.2.5	xxxxxxxxx	2000	Calculation of the 1x dosage rate for deltamethrin in a ruminant livestock feeding study C009557 Non GLP	Y	Aventis
KCA 6.2.2-6.2.5	xxxxxxxxx	2001	Survey of Reports on Analysis for Deltamethrin in Milk from Cows and Humans B003480 Non GLP	Y	Aventis
KCA 6.5.2-6.5.3	Klein E H-J	2001g	Decline of residues in tea and processed fractions South East Asia 200/2001 Deltemethrin AE F032640 emulsifiable concentrate (EC) 2.81 % w/w (=25 g/L) Raport No. C016591 Aventis CropScience, Residues and Human exposure, Frankfurt, Germany GLP, Unpublished	N	Aventis
KCA 6.5.2-6.5.3	Klein E H-J and Martens R	2000e	Residues at harvest in olives and processed fractions European Union, Southern zone 1997 Deltamethrin AE F032640 Emulsifiable granule (EG) 6,25 % w/w Report No. C010147 Aventis Crop Science GmbH, Residues and human Expousre Frankfurt Germany GLP, Unpublished	N	Aventis
KCA 6.5.2-6.5.3	Brady SS	1999a	Magnitude of Deltamethrin Residues in or on Tomatoes and Processed Tomato Commodities Resulting from six applications of Decis Insecticide USA, 1998 Report No. C002859	N	AgrEvo

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			AgrEvo USA Company, Pikeville, North Carolina		
KCA 6.5.2-6.5.3	Maurer T.	2001	Investigation of the Nature of the potential residue in products of Industrial processing or Household Preparation. Report No. C017397 Aventis CropScience, Fraknfurt am Main Germany	N	Aventis
KCA 6.6.2	Krebs, Eickhoff, and Raquet	1986	Deltamethrin - Bestimmung von Rueckstaenden in Gemuesekulturen nach Aufnahme aus kontaminiertem Boden Generated by: Hoechst AG, Landwirtschaftliche Entwicklungsabteilung, Frankfurt, Germany Company file No: DE34266 Non-GLP, Unpublished	N	Aventis

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.6.1	Philip Rooney	2019	[¹⁴ C]-IM-1-5: Metabolism in Rotational Crops FR/000939 Fera Science Limited Centre for Chemical Safety & Stewardship Sand Hutton York YO41 1LZ UK GLP Unpublished	N	Chemrol

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Acetamiprid

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

Comments of zRMS:	Freezer storage stability experiments were initially conducted in study ACI19-002, Phase FR/000938 with the final time points being completed in the current study. For each time point, duplicate samples were fortified at 0.1 mg/kg (10 x LOQ). The freezer storage stability time point for spring cereal plant and spring cereal grain was analysed, extending the data for spring cereal plant and spring cereal grain to cover up to 157 and 149 days freezer storage, respectively. In the description of the study, the Applicant quotes tables that are not included in the description of the study available below, they are available only in the report. The study is accepted.
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Reference:	KCP 6.1
Report	Completion of Analysis of Samples Generated in Study Number ACI19-002, 2021, Gordon Turnbull, Study Number: FR/000938-10
Guideline(s):	The study was conducted in compliance with the United Kingdom Good Laboratory Practice Regulations 1999 Statutory Instrument No. 3106 and the 2004 codification amendment Statutory Instrument 994. These regulations are in accordance with the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice 1997 [ENV/MC/CHEM (98) 17] which are accepted by regulatory authorities throughout the European Community, The United States of America (United States Environment Protection Agency, FIFRA, Title 40 CFR Part 160) and Japan (Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals [Ordinance of the Ministry of Agriculture, Forestry and Fisheries No. 76, 2018]) on the basis of intergovernmental agreements.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Study ACI19-002 presented freezer storage stability data for spring cereal plant and spring cereal grain covering up to 135 and 83 days, respectively. An additional time point for each of these commodities was analysed in the current study, extending the data for spring cereal plant and spring cereal grain to cover up to 157 and 149 days, respectively. These data are presented in the table below. For crop samples, the time points cover the maximum freezer storage periods for all commodities in study ACI19-002. The maximum freezer storage period for soil field trial samples analysed in study ACI19-002 and the current study was 371 days. Study ACI19-002 presented storage stability data for soil up to 347 days. An

additional time point for soil was analysed in the current study, extending the data for soil to cover up to 452 days. These data are presented in Table 10. The time point stated in Table 10 covers the maximum freezer storage periods for the soil field samples analysed in study ACH9-002 and in the current study. The data in Tables 9 and 10 suggest that acetamiprid, IM-1-4 and IM-1-5 are stable in the frozen commodities over the time periods tested. Some recovery values in the final time point of the stored samples tend to be high (> 120%). This could be due to slow desiccation of the sample matrix and/or changes in matrix effects on extended storage of the samples.

Commodity	Analyte	Storage period (days)	Recovery in freezer storage stability sample (% range plus mean)	Procedural recovery for freshly spiked control sample (%)
Spring cereal, plant *	acetamiprid	157	139, 148 (143)	103
	IM-1-4	157	80, 88 (84)	91
	IM-1-5	157	111, 113 (112)	109
Spring cereal, grain **	acetamiprid	149	141, 141 (141)	95
	IM-1-4	149	88, 91 (90)	99
	IM-1-5	149	117, 122 (120)	108

Comments of zRMS:	The study was evaluated and accepted in dRR Part B7 for CHR/I/ACE 200 SE.
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Reference:	KCA 6.1
Report	Acetamiprid in cereal grain - stability study, 2021, Niewelt, S., Study Number: DPL/01/2021
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/2000 Guidance document on pesticide residue analytical methods, SANCO/825/00 rev. 8.1, 16/11/2010 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830, Rev.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Blank and fortification samples

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

One sample blank matrix and two procedural recoveries at the level of 0.10 mg/kg per analytical set of respective matrix were analyzed during each of the sequence.

The following results for fortified samples were obtained during analysis.

Table 10 Quality control samples

Sample Name	Commodity	Result (mg/kg)	Recovery (%)
DPL-01-2021, P0.lcd	wheat grain	<LOD	-
DPL-01-2021, PK1 0,10 mg-kg.lcd	wheat grain	0.10	100.3
DPL-01-2021, PK2 0,10 mg-kg.lcd	wheat grain	0.10	104.3

The following results for fortified samples were obtained during analysis on 10.09.2021:

Table 11 Quality control samples

Sample Name	Commodity	Result (mg/kg)	Recovery (%)
DPL-01-2021, P0.lcd	wheat grain	<LOD	-
DPL-01-2021, PK1 0,10 mg-kg.lcd	wheat grain	0.10	103.6
DPL-01-2021, PK2 0,10 mg-kg.lcd	wheat grain	0.10	102.0

Results

The method was validated according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines.

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and $RSD \leq 20\%$ for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for wheat grain.

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of acetamiprid in wheat (grain) meets the criteria of SANCO/3029/99, rev. 4 guidelines, SANCO/825/00 rev. 8.1., 16/11/2010 and SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

Commodity	Analyte	Storage Period (days)	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
wheat grain	acetamiprid	0	-	-	100.3 104.3
wheat grain	acetamiprid	200	0.092 0.092 0.091	91.7 92.2 90.6	103.6 102.0

A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.1.1.2.1 Study 1

Comments of zRMS:	The study is accepted. Results shows that residues of acetamiprid are stable over the period of 37 days.
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Reference:	KCP 6.1
Report	Frozen Storage Stability of Residues of Acetamiprid in honey, 2022, Faessel, V., Study Number: C1310
Guideline(s):	Regulation (EC) No. 1107/2009 SANTE/2020/12830, Rev. 1 ENV/JM/MONO(2007)17 OECD 506
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study was to generate data about the stability of residues of Acetamiprid in Honey upon deep freezing storage conditions (below -18°C). Samples supplemented with Acetamiprid were analysed after 0 and at 37 days of frozen storage to cover storage period of the specimens from trial C0280 PL1.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOP PG 0115.
 The amount required by the analytical method (5 g) was weighed from the Honey sample (stored at ~+4°C before use).
 Supplementation
 Different aliquots were supplemented independently at 10 x LOQ with acetamiprid.
 Supplemented aliquots were prepared in duplicate for all series.
 Some aliquots were kept without supplementation to be analysed as control samples and procedural spiked samples.
 Storage

The supplemented aliquots were stored frozen at a temperature below -18°C until analysis (series S(35), except the aliquots that were analysed on the day of supplementation (series S(0)).

No.	Study sample code	Sample type	Specimen Reception	Extraction Date	Analysis Date
1	20-00228-01 1	sweet peppers	28.10.2020	13.11.2020	13.11.2020
2	20-00228-01 2	sweet peppers	28.10.2020	13.11.2020	13.11.2020
3	20-00228-01 3	sweet peppers	28.10.2020	13.11.2020	13.11.2020
4	20-00228-01 4	sweet peppers	28.10.2020	13.11.2020	13.11.2020

Extraction

Water is added to the homogenized sample (5 g for honey, 2.5 g for pollen) which is then extracted with acetonitrile/acetic acid 99.9:0.1%. After addition of MgSO₄, NaCl, and buffering citrate salts (pH 5-5.5).

the mixture is shaken intensively and centrifuged for phase separation. An aliquot of the organic phase is cleaned-up by:

- dispersive PSA addition,

- MgSO₄ addition,

Before analysis, the extract is diluted with the acetonitrile/acetic acid 99.9:0.1% mixture.

The analysis was done with LC-MS/MS.

Fortification and control samples

Limits of detection and quantification are determined according to SOP NO. PG 0121.

LOD

The limit of detection (LOD) was expressed as lowest calibration standard.

The LOD was 0.75 ng/mL for acetamiprid in honey (corresponding to 0.003 mg/kg).

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey (see validation study C0238).

Results

The residues in all control samples were below the limit of quantification of the analytical method. The analytical results for storage stability are summarised in the table below.

Matrix	Storage Time (days)	ANADIAG Sample No.	Nominal value (A) (µg/kg)	Amount found (B) Acetamiprid (µg/kg)	% of nominal value (B/A)	Average of % of nominal value Acetamiprid	Procedural recovery
Honey	0	C1310 01 02 11	101.18	102.41	101.2%	98.1%	99.1%
		C1310 01 03 11	101.18	96.17	95.0%		
	37	C1310 01 07 11	101.18	100.97	99.8%	97.2%	96.1%
		C1310 01 08 11	101.18	95.66	94.5%		

Conclusions

The stability of acetamiprid upon deep frozen storage (temperature below -18°C) was evaluated in honey.

For acetamiprid, residues are sufficiently stable over the period of 37 days in honey.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

No new studies submitted

A 2.1.2.1.1 Nature of residue in primary crops

No new studies submitted

A 2.1.2.1.2 Nature of residue in rotational crops

A 2.1.2.1.2.1 Study 1

Comments of zRMS:	The study was not evaluated in the framework of this assessment. It has been previously evaluated and accepted in the dRR part B7 for extension of authorization for CHR/I/ACE (zRMS PL, finalisation date 08/03/2022).
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Reference:	KCA 6.6.1
Report	[¹⁴ C]-IM-1-5 Metabolism in Rotational Crops, Philip Rooney, 2019, FR/000939
Guideline(s):	OECD 502: Metabolism in Rotational Crops (2007)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Materials and methods

The field phase of the study was conducted indoors at AgroChemex, Manningtree, Essex. The soil for use in this study was obtained by the Test Site. A sample of soil was characterised by Bailey's of Norfolk. The sample of soil was characterised for particle size distribution. The results are included in appendix 5 and was conducted outside of the scope of this study. A single application was made to soil containers, pre-filled with the soil (FERA ACE18-173-0- 1). The actual rate of application was 0.311 kg/ha and at a spray volume of 280 L/ha. The application was made using a spray device based on a single cone nozzle. A water rinse of the spray equipment was applied immediately following application to the soil. A detailed description of spraying apparatus is available in appendix 6. The containers were enclosed within closed spray chambers lined with polyethylene sheeting during application which took place on the 18th December 2018. The spray apparatus and plastic sheeting were returned to the test facility and the amount of radioactive residues were measured confirming successful application of the test item application solutions. On the day of application, following the application, Wheat, turnip and spinach crops were planted in separate treated tubs. Following growth, the planted crops were sampled and shipped to the test facility for analysis. Samples were stored frozen prior to analysis. When required crops were removed from storage, homogenised and a sub-sample was taken and oxidised to determine total recovered radioactivity. If more than 0.01 mg Kg-1 was determined from the sample oxidiser process, then the sample type was taken for radioactive characterisation via extraction and liquid scintillation counting (LSC), an potentially high pressure liquid chromatography connected to ultra violet detection coupled to a beta radioactivity analysis module (HPLC-UV-βRAM) or thin layer chromatography (TLC) analysis.

Deviations:

Requirement	Deviation	Impact on integrity of study
Chemical name of test item was noted as N-((6-chloropyridin-3-yl)methyl)-N-methylacetimide within the study plan.	The supplied test item was N-(((6-chloro-3-[pyridy-2,6- ¹⁴ C])methyl)-N-methyl acetamidine hydrochloride. It is also noted that the position of the C14 isotopes had deviated from the study plan.	<p>Whilst discrepancies were noted and a deviation from the study plan has occurred, none of the discrepancies are critical.</p> <p>Test item was supplied as a hydrochloride salt to aid solubility when prepared in solution. If the application solution had been made with either the hydrochloride salt or the free base form referenced in the study plan, the test item in either of these forms would have existed as the same state in solution.</p> <p>The discrepancy noted between relative molecule mass is due to the inclusion of the hydrochloride salt in the final test item supplied.</p>
Section 6.1, If the CV obtained from the analysis is <10% the results will be considered satisfactory.	The detail within the study plan contradicts the standard operating procedure in error. A relative standard deviation of <20% was used to assess the validity of the combustion process for triplicate aliquots taken for a sample.	Whilst the standard operating procedure used has a more lenient validity criteria than the study plan, see section 6.1 there is no scientific basis for the < 10 % CV requirement. The combustion process is subject to variability due to the nature of the apparatus. This deviation has had no notable impact on the validity of the study.
Soil will be sent for analysis at a separate facility. This will be performed and reported in a separate study.	A sample of soil was sent to Baileys of Norfolk, only the particle size distribution assessment was performed in error. No assessment of specific clay or silt content was performed. A combined clay and silt content was determined.	The textural class was determined in study using the Soil texture triangle diagram. The soil was either a sandy loam or sandy clay loam. pH, organic matter were to be performed and reported in a separate study. As these parameters are not critical there has been no impact on this study.
The radiochemical purity of the test item sent to AgroChemex for application will be measured chromatographically and should be >97%.	The application solution was assessed in duplicate prior to application and the mean result was 96.48%. This result is below the instruction within the study plan.	The requirement stated within the study plan is over and above the requirement stated within the OECD 502 (2007) guidance document that this study has been conducted in accordance with. The guidance requires that justification of test item used below 95% purity needs to be explained. However, in this case the test item remained above 95% prior to and post application. Therefore the SD is confident that the study has not been negatively impacted.
To identify major components (metabolites) of the TRR >0.05 ppm or >10% TRR and characterise those between 0.01 – 0.05 ppm as appropriate.	For Wheat Hay, 24.68 % of the total radioactive residues remained bound to the post extraction residues. However, this accounts for only 0.005 mg Kg ⁻¹ of test item which is below the trigger value detailed in the OECD 502 (2007) guidance document.	Whilst, 24.68 % is above the % TRR trigger level, a minor amount of radioactivity would be liberated during any further extraction making the analysis overly complex and unreliable. This deviation from the study plan has not had a notable impact on the outcome of the study.

Results and discussion

Minor residues were detected within the application apparatus therefore there is no concern regarding the application process and deemed satisfactory. Determination of radioactive residues within Wheat Forage, Hay, Grain and Leaves, Turnip leaves and Roots, and mature and immature spinach was performed. Wheat forage, hay and straw, turnip leaves and roots demonstrated radioactive residues above 0.01 mg Kg⁻¹. These sample types were taken forward for extraction and analysis. Further extraction and analysis was performed on Wheat Straw as more than 0.01 mg Kg⁻¹ remained within the post extraction residues. After reliable HPLC-UV-βRAM analysis all radioactivity was shown to be parent, IM-1-5.

Table A 1: Mean total radioactivity recovered from Wheat, spinach and turnip.

Crop	Raw Agricultural Commodity	Total Radioactivity Recovered ^a		Trigger for further analysis (OECD 502, 2007)
		MBq kg ⁻¹	Mg Kg ⁻¹	
Wheat	Forage	0.058	0.018	YES
	Hay	0.059	0.018	YES
	Grain	0.026	0.008	NO
	Straw	0.321	0.098	YES
Turnip	Leaves	0.155	0.047	YES
	Roots	0.337	0.102	YES
Spinach	Immature	0.013	0.004	NO
	Mature	0.028	0.009	NO

a – Mean of the total radioactivity calculated from triplicate aliquots taken of the homogenised sample type.

Table A 10: Summary of the mean extracted and bound residues after stage one extraction

Crop	Raw Agricultural Commodity (RAC)	Extraction Number 1		Post Extraction Solids (PES)		Mass Balance
		% TRR	Mg Kg ⁻¹	% TRR	Mg Kg ⁻¹	(% of TRR)
Wheat	Forage	86.37	0.015	8.19	0.002	94.55
	Hay	82.32	0.015	24.68	0.005	107.00
	Straw ^a	83.28	0.082	22.26	0.022	105.53
Turnip	Leaves	110.14	0.052	2.09	0.001	112.22
	Roots ^a	94.51	0.097	0.98	0.001	95.50

a – Mean of the total radioactivity calculated from six aliquots taken of the homogenised sample type.

Table A 2: HPLC-UV-βRAM mean summary data for RAC's, Extract 1

Crop	Raw Agricultural Commodity (RAC)	Parent (% TAR)	IM-1-4 (% TRR)	Total Unknowns < 10 % of TAR (% TAR)	Largest Unknown < 10 % of TAR (% TAR)	RT of largest unknown (mm:ss)	Unresolved background (%)	Total Recovered Radioactivity (%)
Wheat	Forage ^a	85.20	ND	ND	ND	NA	4.29	89.49
	Hay ^a	87.58	ND	13.37	3.21	16:50	4.40	105.35
	Straw	77.15	ND	1.51	2.31	14:30	4.08	83.28
Turnip	Leaves	105.22	ND	ND	ND	NA	4.95	110.17
	Roots	92.25	ND	ND	ND	NA	4.76	97.02

NA – Not applicable as analysis not conducted or not valid, ND – No radioactivity residues detected. a – Due to the formation of an experimental artefact, see section 3.2, value is based on one replicate only.

Table A 3: Summary of stage 2 extraction and post extraction solid analysis.

Crop	Raw Agricultural Commodity	PES (Stage 1)	Extraction Number 2 (Acidic Reflux)		Extraction Number 3 (Basic)		PES (Stage 2)	
		% TRR	% TRR	Mg Kg ⁻¹	% TRR	Mg Kg ⁻¹	% TRR	Mg Kg ⁻¹
Wheat	Straw ^a	22.26	11.17	0.011	3.05	0.003	4.44	0.004

a – Mean of the total radioactivity calculated from six ca. 25 g aliquots taken of the homogenised sample type.

Figure A 1: Proposed Metabolic route of IM-1-5 in rotational crops

All radioactive residues detected via HPLC-UV-βRAM within each crop and sample type co-eluted with an IM-1-5 analytical reference material. Therefore, no metabolism pathway can be deduced.

Conclusions

IM-1-5 is the primary metabolite present in soil after the application of its parent, acetamiprid. Immediately after application, crops were planted into the treated soil. [¹⁴C]-IM-1-5 remained the only observed component within all HPLC-UV-βRAM and TLC analyses. Minor uptake of IM-1-5 was observed for spinach and Wheat grain. IM-1-5 residues within these sample types were below the 0.01 mg Kg⁻¹ trigger. Some notable uptake of the test item was observed for Wheat Forage Hay and Straw. Residues were also detected in turnips above the 0.01 mg Kg⁻¹ trigger. Radioactive residues were extracted successfully from all RACs and after HPLC-UV-βRAM were determined to be parent IM-1-5 which was determined via co-elution with an analytical standard. After the initial extraction using acetonitrile:water (1:1 v/v), 24.68 % of the total radioactive residues remained bound to Wheat Hay and 22.26 % bound to Wheat Straw. However, due to low amount of uptake into the Wheat Hay, 22.26 % only represented 0.005 mg Kg⁻¹ , therefore further extraction processes were terminated for this RAC type. Wheat Straw was further extracted using a harsher extraction technique which included an acidic reflux and basic extraction. An additional 11.17 % was removed from the PES using the reflux and 3.05 % using the basic extraction. Due to the low level of radioactivity, analysis of the acidic reflux was conducted using TLC, however no detection of the radioactivity was possible. No further analysis of the stage 2 PES was conducted as only 4.44 % of the Total Radioactive residues remained bound. It is assumed that the remaining radioactive residues have been incorporated into biomolecules such as cellulose or lignin which are key structural components within the fibrous material of plant tissues.

A 2.1.2.1.2.2 Study 2

Comments of zRMS:	The study was not evaluated in the framework of this assessment. It has been previously evaluated and accepted in the dRR part B7 for extension of authorization for CHR/I/ACE (zRMS PL, finalisation date 08/03/2022).
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Reference: KCA 6.6.2

Report FIELD ROTATIONAL CROP STUDY (SPRING CEREAL, SPINACH AND TURNIPS) WITH A SUSPO EMULSION FORMULATION CONTAINING 200 G/L ACETAMIPRID APPLIED TO BARE SOIL AT 365, 120, 70 AND 30 DAYS PRIOR TO PLANTING THE ROTATIONAL CROPS IN THE UNITED KINGDOM AND SPAIN, 2019/2020, Ignacio

Palau, 2021, Report Number: ACI19-002

Guideline(s):	OECD guideline for the testing of chemicals No. 509, “Crop Field Trial” (07/09/2009). OECD guideline for the testing of chemicals No. 504, “Residues in Rotational Crops (Limited Field Studies)” (08/01/2007). Guidance document SANCO/3029/99 rev.4 (11/07/00). OECD Series on Testing and Assessment No. 72 and Series on Pesticides No. 39 “Guidance document on pesticide residue analytical methods”, ENV/JM/MONO(2007)17 (13/08/2007)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Method and results:

The rotational crops were planted at nominal intervals of 365 ± 5 , 120 ± 3 , 70 ± 3 and 30 ± 2 days after a single application to bare soil at a nominal rate of 300 g a.s./ha of a 200 g/L SE formulation of acetamiprid. Raw agricultural commodity samples were generated from spring cereal, spinach and turnips harvested from treated and non-treated plots as soon as sufficient plant material was available (BBCH 13 to 15), hay sampling (spring cereal only), at the earliest possible commercial harvest (spinach and turnips only) and at normal commercial harvest of the crops. Crop samples taken as soon as sufficient plant material was available consisted of whole plants (≥ 500 g for spinach and turnips and ≥ 1 kg for cereal) cut above the soil. Cereal samples taken for hay (≥ 500 g) consisted of whole plants cut above the soil (BBCH 75) and field dried to a moisture content of 10 to 20%. Cereal samples taken at normal commercial harvest consisted of grain (≥ 1.0 kg) and straw (≥ 500 g) obtained from at least 12 different areas within each plot. The straw was cut approx. 15 cm above the soil. The samples were collected using a small plot combine (UK) or manual threshing (Spain). Spinach samples taken at earliest commercial harvest and commercial harvest consisted of at least 12 spinach plants (≥ 1 kg). The plants were cut above the soil. Turnip samples taken at earliest commercial harvest and normal commercial harvest consisted of at least 12 turnips (≥ 2 kg). The tops/leaves were separated from the roots and analysed separately. Soil samples for residue analysis were taken on the day of application (within 3 hours of application), on the day of planting the rotational crop, as soon as sufficient plant material was available (BBCH 13 to 15) and at normal commercial harvest of each rotational crop. Each sample consisted of 10 cores (> 500 g) taken to a depth of 20 cm. However, to meet the reporting schedule for the regulatory submission deadline, the analysis of the soil samples was terminated at the request of the Sponsor since the soil analysis is not a strict requirement within the OECD guidelines for the conduct of field rotational crop studies. The soil analysis data already generated for the soil samples is presented in the analytical phase report (appendix 5), but will not be discussed further. Each sample was taken in duplicate ('ship' and 'retain'). The 'ship' samples were sent to the analytical laboratory and arrived in good frozen condition. The remaining 'retain' samples were not required for analysis. All samples were shipped using dry ice or in a freezer truck. The analysis was conducted using analytical methods previously developed and validated by Fera Science Ltd. as part of this study. Details of the analytical methods are provided in appendix 4 of the analytical phase report (see appendix 5). The limit of quantification (LOQ) was 0.01 mg/kg for acetamiprid, IM-1-4 and IM-1-5 for all crop matrices. The spiked samples (procedural recoveries) analysed along with the crop samples gave mean recoveries within the acceptable range of 70 to 110% and demonstrate the accuracy of the method on the days of analyses. Residues of acetamiprid and IM-1-5 were less than the LOQ in all crop matrices for both trial sites. Residues of IM-1-4 were less than the LOQ in all crop matrices in Spain, except in one spring cereal sample (at 0.024 mg/kg) and one turnip sample (0.010 mg/kg). Residues of IM-1-4 were less than the LOQ in all crop matrices in the United Kingdom, except one spinach sample (at 0.011 mg/kg) and seven turnip samples which ranged from 0.012 – 0.021 mg/kg.

Deviations:

The following deviations were documented, which have no impact on the integrity of the study: 1. Trial ACI19-002/1 (UK): Due to the wet field conditions in part of the field on the day of the application the length of plot 4 had to be reduced from 30 m to 20 m, therefore the total plot area was reduced from 225 m² to 150 m². 2. For both trials the initial soil characterisation analyses did not include the parameters pH (CaCl₂) and moisture capacity. Therefore, new soil characterisation samples were taken from non-treated areas for both trials at the end of the field sampling phase to determine these missing parameters. The sampling was performed following the same procedure as for the soil characterisation samples taken before the first application.

Results:

ACI19-002/1 (United Kingdom) Spring cereal

	Acetamiprid (mg/kg)			IM-1-4 (mg/kg)			IM-1-5 (mg/kg)		
	Plant	Grain	Straw	Plant	Grain	Straw	Plant	Grain	Straw
Nominal pre-planting interval 30±2 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ
Nominal pre-planting interval 70±3 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ
Nominal pre-planting interval 120±3 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ
Nominal pre-planting interval 365±5 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ

¹ Sufficient plant material available (BBCH 13-15)

² Hay (BBCH 75)

³ Commercial harvest (BBCH 89)

< LOQ – less than the limit of quantification of 0.01 mg/kg

ACI19-002/2 (Spain) Spring cereal

	Acetamiprid (mg/kg)			IM-1-4 (mg/kg)			IM-1-5 (mg/kg)		
	Plant	Grain	Straw	Plant	Grain	Straw	Plant	Grain	Straw
Nominal pre-planting interval 30±2 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ
Nominal pre-planting interval 70±3 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ
Nominal pre-planting interval 120±3 days									
Sufficient plant ¹	<LOQ			0.024			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ
Nominal pre-planting interval 365±5 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
Hay ²	<LOQ			<LOQ			<LOQ		
Commercial harvest ³		<LOQ	<LOQ		<LOQ	<LOQ		<LOQ	<LOQ

¹ Sufficient plant material available (BBCH 13)

² Hay (BBCH 75)

³ Commercial harvest (BBCH 89)

< LOQ – less than the limit of quantification of 0.01 mg/kg

ACI19-002/1 (United Kingdom) Spinach

	Acetamiprid (mg/kg)	IM-1-4 (mg/kg)	IM-1-5 (mg/kg)
	Plant	Plant	Plant
Nominal pre-planting interval 30±2 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ
Nominal pre-planting interval 70±3 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	0.011	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ
Nominal pre-planting interval 120±3 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ
Nominal pre-planting interval 365±5 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ

¹ Sufficient plant material available (BBCH 13-15)

² Earliest commercial harvest (BBCH 18-43)

³ Commercial harvest (BBCH 48-49)

< LOQ – less than the limit of quantification of 0.01 mg/kg

ACI19-002/2 (Spain) Spinach

	Acetamiprid (mg/kg)	IM-1-4 (mg/kg)	IM-1-5 (mg/kg)
	Plant	Plant	Plant
Nominal pre-planting interval 30±2 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ
Nominal pre-planting interval 70±3 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ
Nominal pre-planting interval 120±3 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ
Nominal pre-planting interval 365±5 days			
Sufficient plant ¹	<LOQ	<LOQ	<LOQ
E. commercial harvest ²	<LOQ	<LOQ	<LOQ
Commercial harvest ³	<LOQ	<LOQ	<LOQ

¹ Sufficient plant material available (BBCH 15)

² Earliest commercial harvest (BBCH 45)

³ Commercial harvest (BBCH 49)

< LOQ – less than the limit of quantification of 0.01 mg/kg

ACI19-002/1 (United Kingdom) Turnip

	Acetamiprid (mg/kg)			IM-1-4 (mg/kg)			IM-1-5 (mg/kg)		
	Plant	Roots	Leaves	Plant	Roots	Leaves	Plant	Roots	Leaves
Nominal pre-planting interval 30±2 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ			<LOQ <LOQ			<LOQ <LOQ		
Nominal pre-planting interval 70±3 days									
Sufficient plant ¹	<LOQ			0.012			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ 0.017			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ			<LOQ 0.013			<LOQ <LOQ		
Nominal pre-planting interval 120±3 days									
Sufficient plant ¹	<LOQ			0.012			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ 0.021			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ			<LOQ 0.012			<LOQ <LOQ		
Nominal pre-planting interval 365±5 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ 0.014			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		

¹ Sufficient plant material available (BBCH 15)

² Earliest commercial harvest (BBCH 48-49)

³ Commercial harvest (BBCH 49)

< LOQ – less than the limit of quantification of 0.01 mg/kg

ACI19-002/2 (Spain) Turnip

	Acetamiprid (mg/kg)			IM-1-4 (mg/kg)			IM-1-5 (mg/kg)		
	Plant	Roots	Leaves	Plant	Roots	Leaves	Plant	Roots	Leaves
Nominal pre-planting interval 30±2 days									
Sufficient plant ¹	<LOQ			0.010			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ			<LOQ <LOQ			<LOQ <LOQ		
Nominal pre-planting interval 70±3 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ			<LOQ <LOQ			<LOQ <LOQ		
Nominal pre-planting interval 120±3 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ			<LOQ <LOQ			<LOQ <LOQ		
Nominal pre-planting interval 365±5 days									
Sufficient plant ¹	<LOQ			<LOQ			<LOQ		
E. commercial harvest ²	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		
Commercial harvest ³	<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ			<LOQ <LOQ <LOQ		

¹ Sufficient plant material available (BBCH 15)

² Earliest commercial harvest (BBCH 45)

³ Commercial harvest (BBCH 49)

< LOQ – less than the limit of quantification of 0.01 mg/kg

Method of application:

Each application was made with a research boom sprayer. Prior to the application, the sprayer was calibrated using a catch time of 30 seconds. Output was determined by measuring the delivered volume from each nozzle using a graduated cylinder. The output data was used to calculate the speed required to walk in the plots to give the nominal application volume according to the study plan. Actual application volumes and rates were determined by measuring the start volume and the final volume of spray solution in the spray tank

Sampling:

Non-treated samples were collected prior to taking samples in the treated plots. Gloves were worn and changed between each plot and any sampling equipment was cleaned between each plot. ‘Ship’ and ‘retain’ samples were collected from each plot. The retain samples were a back-up in case of problems during sample shipment for the ‘ship’ samples. The ‘retain’ samples were not required for analysis. Soil samples Soil samples were taken on the following occasions: - On the day of application (treated samples within 3 hours after application) - On the day of planting the rotational crop - As soon as sufficient plant material was available for sampling - At normal commercial harvest of the rotational crop On each sampling occasion, 10 soil cores (>500 g) were taken from each plot with a closed-face soil corer to a

depth of 20 cm. The cores from each plot were combined and thoroughly mixed. This procedure was repeated to provide 'ship' and 'retain' samples. Crop samples were taken on the following occasions: - As soon as sufficient plant material was available for sampling - Hay sampling (spring cereal only) - At earliest commercial harvest of the rotational crop (spinach and turnip only) - At normal commercial harvest of the rotational crop Each crop sample was placed into a polyethylene bag and subsequently double bagged prior to freezing. The samples taken "as soon as sufficient plant material was available" were taken at BBCH 13 to 15. Each sample consisted of whole plants excluding roots (≥ 1 kg for cereal and >500 g for spinach and turnips), cut above the soil. Spring cereal samples taken for hay (>500 g) consisted of whole plants cut above the soil (BBCH 75). The plants for hay were dried naturally to a moisture content of 10 to 20% (hay fractures easily; snaps easily when twisted; juice difficult to extract). The drying process took approximately 8 days in the United Kingdom and approximately 3 days in Spain. Each sample was taken from at least 12 different areas within each plot. Spring cereal samples taken at normal commercial harvest consisted of ≥ 1.0 kg grain and ≥ 0.5 kg straw obtained from at least 12 different areas within each plot. The straw was cut approximately 15 cm above the soil. The spinach samples taken at earliest commercial harvest and normal commercial harvest consisted of at least 12 spinach plants (≥ 1.00 kg). The plants were cut above the soil and any adhering soil was removed by gentle brushing, if required. Any outer decaying/damaged leaves were removed during sampling. The turnip samples taken at earliest commercial harvest and normal commercial harvest consisted of at least 12 turnips (≥ 2.00 kg). The tops/leaves were removed from the roots and each fraction was weighed and sampled separately. Any adhering soil was removed by gentle brushing, if required. Any diseased, poorly developed or injured crop was not sampled. Samples were taken randomly from across the plots, excluding the outer rows. Sample identification labels specified the type of sample, sample identification number and experiment information. Treated and non-treated samples were placed in separate containers for transport to the freezer. All samples were placed into freezer storage within 3 hours after the end of sampling. All sampling equipment, including gloves and bags were dry to avoid unwanted moisture. The sampling was conducted when the crop was dry.

ANALYTICAL PHASE DETAILS

The analysis was conducted using analytical methods previously developed and validated by Fera Science Ltd. as part of this study. Details of the analytical methods are provided in appendix 4 of the analytical phase report (see Appendix 5). The limit of quantification (LOQ) was 0.01 mg/kg for acetamiprid, IM-1-4 and IM-1-5 for all crop matrices. The spiked samples (procedural recoveries) analysed along with the crop samples gave mean recoveries within the acceptable range of 70 to 110% and demonstrate the accuracy of the method on the days of analyses. In order to meet the reporting schedule for the regulatory submission deadline, the duration of the storage stability data within this study does not cover the longest storage duration for the field samples. However, the Sponsor has informed the study director that storage stability has been established for acetamiprid in various crops in a previous study for approximately one year: Souvignet I, Goller G, Duchene P, 1999, Stability study of NI-25 (acetamiprid) in apple and tomato samples after storage in the freezer at or below -18°C . A.D.M.E. Bioanalysis Report No. RPA/NI-25/97051, Document No. RD 00340. In order to meet the reporting schedule for the regulatory submission deadline, the analysis of the soil samples was terminated at the request of the Sponsor since the soil analysis is not a strict requirement within the OECD guidelines for the conduct of field rotational crop studies.

Conclusion:

No residues of acetamiprid, IM-1-4 or IM-1-5 above the limit of quantification of 0.01 mg/kg were detected in any sample analysed from the non-treated plots

A 2.1.2.1.2.3 Study 3

Comments of zRMS:	The study was not evaluated in the framework of this assessment. It has been previously evaluated and accepted in the dRR part B7 for extension of authorization for CHR/I/ACE (zRMS PL, finalisation date 08/03/2022).
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Reference:	KCA 6.6.2
Report	Completion of Analysis of Samples Generated in Study Number ACI19-002, 2021, Gordon Turnbull, Study Number: FR/000938-10
Guideline(s):	The study was conducted in compliance with the United Kingdom Good Laboratory Practice Regulations 1999 Statutory Instrument No. 3106 and the 2004 codification amendment Statutory Instrument 994. These regulations are in accordance with the Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice 1997 [ENV/MC/CHEM (98) 17] which are accepted by regulatory authorities throughout the European Community, The United States of America (United States Environment Protection Agency, FIFRA, Title 40 CFR Part 160) and Japan (Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals [Ordinance of the Ministry of Agriculture, Forestry and Fisheries No. 76, 2018]) on the basis of intergovernmental agreements.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Results:

The results of an additional validation experiment at 1 mg/kg in the 3 study soil types are presented in Tables 1 – 3. Acetamiprid met the SANCO/3029/99 rev.4 criteria in all 3 soils and IM-1-4 and IM-1-5 met the criteria in at least one of the soil types. The maximum acetamiprid residue found in a soil sample was 0.71 mg/kg for spinach (after application) in trial 1 (UK) in the 69 DBP plot. The maximum IM-1-4 residue found in a soil sample was 0.18 mg/kg for spring cereal (day of planting) in trial 1 (UK) in the 119 DBP plot. The maximum IM-1-5 residue found in a soil sample was 0.16 mg/kg for spring cereal (when sufficient plant available) in trial 2 (Spain) in the 68 DBP plot. An additional freezer storage stability time point was analysed for spring cereal plant and spring cereal grain covering up to 157 and 149 days, respectively. An additional freezer storage stability time point for soil was analysed in the current study, extending the data for soil to cover up to 452 days storage.

Study samples:

Study field trial samples were received at Fera from 23 April 2019, with the final shipment being received on 18 August 2020. All samples were received frozen and were transferred to freezer storage on the day of arrival.

Analytical Methods

Method M2V2 was used to analyse soil field trial samples. Method M3V1 was used to analyse spring cereal (whole plant and grain) freezer storage stability samples.

Validation:

In study ACI19-002 the analytical method for soil had been validated at the LOQ (0.004 mg/kg) and at 10 x LOQ. Some residues from the soil field trial samples were > 10 x LOQ, therefore an additional validation level of 1 mg/kg for all 3 analytes in all 3 soil types was conducted in the current study. The results of the validation experiment at 1 mg/kg are presented in Tables 1 – 3. Acetamiprid met the

SANCO/3029/99 rev.4 criteria in all 3 soils and IM-1-4 and IM-1-5 met the criteria in at least one of the soil types. Some of the high recovery values seen for IM-1-4 and IM-1-5 could be due to slow desiccation of the sample matrix and/or changes in matrix effects on extended storage of the control samples used for the validation experiment.

Sample analysis:

Field trial soil samples not analysed in study ACI19-002 were analysed in the current study. The maximum acetamiprid residue found in a soil sample was 0.71 mg/kg for spinach (after application) in trial 1 (UK) in the 69 DBP plot. The maximum IM-1-4 residue found in a soil sample was 0.18 mg/kg for spring cereal (day of planting) in trial 1 (UK) in the 119 DBP plot. The maximum IM-1-5 residue found in a soil sample was 0.16 mg/kg for spring cereal (when sufficient plant available) in trial 2 (Spain) in the 68 DBP plot.

Conclusion:

The remaining soil field trial samples from study ACI19-002 have been analysed and an additional validation level of 1 mg/kg for all 3 analytes was conducted in 3 soil types. Acetamiprid met the SANCO/3029/99 rev.4 criteria in all 3 soils and IM-1-4 and IM-1-5 met the criteria in at least one of the soil types. The maximum acetamiprid residue found in a soil sample was 0.71 mg/kg for spinach (after application) in trial 1 (UK) in the 69 DBP plot. The maximum IM-1-4 residue found in a soil sample was 0.18 mg/kg for spring cereal (day of planting) in trial 1 (UK) in the 119 DBP plot. The maximum IM-1-5 residue found in a soil sample was 0.16 mg/kg for spring cereal (when sufficient plant available) in trial 2 (Spain) in the 68 DBP plot (ACI19-002 data, see Appendix 5). An additional freezer storage stability time point for spring cereal plant and spring cereal grain was analysed in the current study, extending the data for spring cereal plant and spring cereal grain to cover up to 157 and 149 days freezer storage, respectively. An additional freezer storage stability time point for soil was analysed in the current study, extending the data for soil to cover up to 452 days freezer storage.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies submitted

A 2.1.2.2 Nature of residues in livestock

No new studies submitted

A 2.1.3 Magnitude of residues in plants

Cereals summary for SE formulation:

Report-No. Location	Commodity	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i./ha	Water l/ha	Kg a.i./hl						
20SGS15, Nyirtelek, Hungary	Winter wheat	1) 12.10.2019 2) 08.07.2020	0.0388	290	0.0134	08.06.2020	BBCH 75	Grain	<0.003	24	LOQ = 0.010 mg/kg The study results were not used in the evaluation. Max. storage interval between sampling and analysis: about 7 months. Stability studies cover only 149 days for grains.
			0.0404	303.3	0.0133	14.06.2020	BBCH 77	Straw	<0.01		
20SGS13, Germany (Brandenburg)	Winter wheat	1) 25.10.2019 2) 27.07.2020	0.0414	206.7	0.0200	22.06.2020	BBCH 75	Grain	<0.01	28	LOQ = 0.010 mg/kg The study results were not used in the evaluation. Max. storage interval between sampling and analysis: about 6 months. Stability studies cover only 149 days for grains.
			0.0386	193.3	0.0200	29.06.2020	BBCH 83	Straw	0.29		
20SGS12, Poland, Kujawsko-Pomorskie	Winter wheat	1) 24.09.2019 2) 06.08.2020	0.0404	303.3	0.0133	22.06.2020	BBCH 75	Grain	<0.003	37	LOQ = 0.010 mg/kg The study results were not used in the evaluation. Max. storage interval between sampling and analysis: about 6 months. Stability studies cover only 149 days for grains.
			0.0412	309.1	0.0133	30.06.2020	BBCH 77	Straw	0.047		
21SGS33/ H-3387, Maklar, Heves, Hungary/2020	Winter wheat/Genius	1) 13.10.2020 2) - 3. 23.07.2021	1) 0.0413 2)	1) 310 2)303.3	1) 0.133 2)0.133	1) 16.06.2021 2) 23.06.2021	1) BBCH 75 2)BBCH	Grain	<LOD	30	The study results for grain were used in the evaluation. Max. storage interval between sampling and analysis: about 3

			0.0404				77	Straw	0.52		months. Stability studies cover 149 days for grains. Grain: 1 x < 0.003 mg/kg
21SGS32/55-216, Piskorówek, Dolnośląskie, Poland/2020	Winter wheat/JULIUS	1. 05.11.2020 2. 09.08.2021	1) 0.0404 2) 0.0396	1) 302.7 2) 297.3	1) 0.133 2) 0.133	1) 01.07.2021 2) 07.07.2021	1) BBCH 75 2) BBCH 77	Grain Straw	<LOD 0.066	33	The study results for grain were used in the evaluation. Max. storage interval between sampling and analysis: about 3 months. Stability studies cover 149 days for grains. Grain: 1 x < 0.003 mg/kg

zRMS comments:

Comparison of intended and critical EU GAPs:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (kg a.s./ha)	PHI (days)
Wheat (code 0500090)				
cGAP EU EFSA Journal 2016;14(2):4385	BBCH 51-79	2 (14 days)	0.042	28
Intended GAP (major use No 3, wheat)	BBCH 37-75	1	0.04	n/a
Intended GAP (major use No 4, triticale)	BBCH 37-75	1	0.04	n/a

A 2.1.3.1.1 Study 1

Comments of zRMS:	<p>One trial was established in Hungary. Two applications were performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) + 0.1 l/ha Asystent+ in BBCH 75 (first application) and BBCH 77 (second application). Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.003 mg/kg and 0.01 mg/kg respectively.</p> <p>Residues of acetamiprid were below LOQ in all samples (wheat grain and straw). The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP), two applications instead of one and with the addition of an adjuvant.</p> <p>The study results were not used in the evaluation. Max. storage interval between sampling and analysis: about 7 months. Stability studies cover only 149 days for grains. Stability study for acetamiprid covers storage time.</p> <p>The study can support the proposed use in wheat.</p>
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Reference:	KCA 6.3
Report	Magnitude of the residue of acetamiprid in Winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one harvest trial in Hungary – 2020. Tomasz Peda, 2021, 20SGS15
Guideline(s):	<p>OECD Guidline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>SANCO/825/00, rev. 8.1; 16/11/2010</p> <p>SANCO/3029/99, rev. 4; 11/07/2000</p>
Deviations:	Yes

GLP: Yes

Acceptability: Yes

Deviations:

Calibration runs during the first and second application were shorter than 30 sec. This deviation did not have an impact on the final result.

Materials and Method:

Field trial was established on representative for winter wheat production, grown in a typical way in the test countries. Trial consisted of one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. For untreated and treated plots they consisted of minimum 30m² for harvest trial. Around the treated and untreated plots a buffer zone (zone where no forbidden products are applied) of at least 10m was set up. The untreated plot was separated by a buffer zone of at least 10 m from treated plot.

The application equipment consisted of boom sprayer.

The foliar applications closely simulated commercial-type treatments.

Calibrations of the spray equipment at the trial site were accomplished by using the volume/time method for liquid applications.

Before each application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

CHR/I/ADEL 200 SE was mixed with water and adjuvant asystent+ (0.1 l/ha) which was added to the spray mixture. The target dose rate of the test item for the study was 0.2 l/ha of formulated product (FP) per application, equivalent to 40 a.s./ha of acetamiprid. Applications were made at a target water volume of 200-300 l/ha of mixture according to good agricultural practice.

Specimen collection:

In harvest study trial (Harvest Study – HS), RAC specimens were collected following the target schedule below:

Plot number	Specimen Id		Sampling occasion	Specimen type	Minimum sample size	Storage Condition
U	20SGS15-01	1	S1 = CH*	Grain	1 kg	frozen
U	20SGS15-01	1R			1 kg	frozen
T	20SGS15-01	2			1 kg	frozen
T	20SGS15-01	2R			1 kg	frozen
U	20SGS15-01	3		Straw	0,5 kg	frozen
U	20SGS15-01	3R			0,5 kg	frozen
T	20SGS15-01	4			0,5 kg	frozen
T	20SGS15-01	4R			0,5 kg	frozen

*CH – Commercial Harvest

RAC specimens were collected from the central parts of the plots.

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues [mg/kg] acetamiprid
20SGS15-01 1	S1 = CH*	Grain	DPL/105/2020/01U	<LOD
20SGS15-01 2			DPL/105/2020/02T	<LOD
20SGS15-01 3		Straw	DPL/105/2020/03U	<LOD
20SGS15-01 4			DPL/105/2020/04T	<LOQ

*CH – Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

Blank and fortification samples:

Quality control samples (grain)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0089	89.1
PK1 0,10 mg-kg.lcd	0.10	100.8
PK2 0,010 mg-kg.lcd	0.0090	90.2
PK2 0,10 mg-kg.lcd	0.11	106.6

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Quality control samples (straw)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0088	88.8
PK1 0,10 mg-kg.lcd	0.10	99.7
PK2 0,010 mg-kg.lcd	0.0088	88.1
PK2 0,10 mg-kg.lcd	0.11	107.6

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

This study was fully performed as anticipated, in accordance with the study plan and the amendments issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). Method of determination by LC-MS fulfils the requirements as defined in EC guidance document on residue analytical methods (SANCO/825/00, rev. 8.1. and SANCO/3029/99 rev. 4) and is applicable as enforcement and data generation method for determination of acetamiprid in winter wheat after two applications of CHR/I/ACE 200 SE. Residues of active ingredients acetamiprid were not detectable (<LOD) in any of the untreated samples.

A 2.1.3.1.2 Study 2

Comments of zRMS:	<p>One trial was established in Germany in 2020. Two applications were performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) + 0.1 l/ha Asystent+ in BBCH 75 (first application) and BBCH 83 (second application). Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.003 mg/kg and 0.01 mg/kg respectively.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid. In the decline studies, residues in grain were below the LOQ of 0.01 mg/kg and 0.29 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP), two applications instead of one and with the addition of an adjuvant.</p> <p>The study results were not used in the evaluation.. Max. storage interval between sampling and analysis: about 6 months. Stability studies cover only 149 days for grains.</p> <p>Stability study for acetamiprid covers storage time.</p> <p>The study can support the proposed use in wheat.</p>
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Reference:	KCA 6.3
Report	Magnitude of the residue of acetamiprid in Winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one decline curve trial in Germany – 2020. Tomasz Peda, 2021, 20SGS13
Guideline(s):	<p>OECD Guidline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>SANCO/825/00, rev. 8.1; 16/11/2010</p> <p>SANCO/3029/99, rev. 4; 11/07/2000</p>
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Method:

Field trial was established on representative for winter wheat production, grown in a typical way in the test countries. Trial consisted of one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. For untreated and treated plots they consisted of minimum 45m² for decline curve trial. Around the treated and untreated plots a buffer zone (zone where no forbidden products are applied) of at least 10m was set up. The untreated plot was separated by a buffer zone of at least 10 m from treated plot.

The application equipment consisted of boom sprayer.
 The foliar applications closely simulated commercial-type treatments.

Calibrations of the spray equipment at the trial site were accomplished by using the volume/time method for liquid applications.

Before each application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

CHR/I/ADEL 200 SE was mixed with water and adjuvant asystent+ (0.1 l/ha) which was added to the spray mixture. The target dose rate of the test item for the study was 0.2 l/ha of formulated product (FP) per application, equivalent to 40 a.s./ha of acetamiprid. Applications were made at a target water volume of 200-300 l/ha of mixture according to good agricultural practice.

Specimen collection:

Plot number	Specimen Id		Sampling occasion	Specimen type	Minimum sample size	Storage Condition
U	20SGS13-01	1	S1 = 0 DALA*	Whole plant without root	12 units, 0,5 kg	frozen
U	20SGS13-01	1R			12 units, 0,5 kg	frozen
T	20SGS13-01	2			12 units, 0,5 kg	frozen
T	20SGS13-01	2R			12 units, 0,5 kg	frozen
T	20SGS13-01	3	S2 = 7(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS13-01	3R			12 units, 0,5 kg	frozen
T	20SGS13-01	4	S3 = 14(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS13-01	4R			12 units, 0,5 kg	frozen
T	20SGS13-01	5	S4 = 21(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS13-01	5R			12 units, 0,5 kg	frozen
U	20SGS13-01	6	S5 = CH*	Grain	1 kg	frozen
U	20SGS13-01	6R			1 kg	frozen
T	20SGS13-01	7			1 kg	frozen
T	20SGS13-01	7R			1 kg	frozen
U	20SGS13-01	8		Straw	0,5 kg	frozen
U	20SGS13-01	8R			0,5 kg	frozen
T	20SGS13-01	9			0,5 kg	frozen
T	20SGS13-01	9R			0,5 kg	frozen

*CH – Commercial Harvest

*DALA – Days After Last Application

RAC specimens were collected from the central parts of the plots.

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues [mg/kg] acetamiprid
20SGS13-01 1	S1 = 0 DALA*	Whole plant	DPL/103/2020/01U	<LOD
20SGS13-01 2			DPL/103/2020/02T	1,0
20SGS13-01 3	S2 = 7(±1) DALA*	Whole plant	DPL/103/2020/03T	0,30
20SGS13-01 4	S3 = 14(±1) DALA*	Whole plant	DPL/103/2020/04T	0,15
20SGS13-01 5	S4 = 21(±1) DALA*	Whole plant	DPL/103/2020/05T	0,17
20SGS13-01 6	S5 = CH*	Grain	DPL/103/2020/06U	<LOD
20SGS13-01 7			DPL/103/2020/07T	<LOQ
20SGS13-01 8		Straw	DPL/103/2020/08U	<LOD
20SGS13-01 9			DPL/103/2020/09T	0,29

*DALA – Days After Last Application.

*CH – Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

Blank and fortification samples:

Quality control samples (grain)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0089	89.1
PK1 0,10 mg-kg.lcd	0.10	100.8
PK2 0,010 mg-kg.lcd	0.0090	90.2
PK2 0,10 mg-kg.lcd	0.11	106.6

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Quality control samples (whole plant without root)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0097	96.8
PK1 0,10 mg-kg.lcd	0.11	107.5
PK2 0,010 mg-kg.lcd	0.0097	97.5
PK2 0,10 mg-kg.lcd	0.11	107.3

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Quality control samples (straw)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0088	88.8
PK1 0,10 mg-kg.lcd	0.10	99.7
PK2 0,010 mg-kg.lcd	0.0088	88.1
PK2 0,10 mg-kg.lcd	0.11	107.6

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

This study was fully performed as anticipated, in accordance with the study plan and the amendments issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). Method of determination by LC-MS fulfils the requirements as defined in EC guidance document on residue analytical methods (SANCO/825/00, rev. 8.1. and SANCO/3029/99 rev. 4) and is applicable as

enforcement and data generation method for determination of acetamiprid in winter wheat after two applications of CHR/I/ACE 200 SE.

A 2.1.3.1.3 Study 3

Comments of zRMS:	<p>One trial was established in Poland in 2020. Two applications were performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) + 0.1 l/ha Asystent+ in BBCH 75 (first application) and BBCH 77 (second application). Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.003 mg/kg and 0.01 mg/kg respectively.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid. Residues in grain were below the LOD and at the level of 0.047 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP), two applications instead of one and with the addition of an adjuvant.</p> <p>The study results were not used in the evaluation.. Max. storage interval between sampling and analysis: about 6 months. Stability studies cover only 149 days for grains.</p> <p>Stability study for acetamiprid covers storage time.</p> <p>The study can support the proposed use in wheat.</p>
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Reference:	KCA 6.3
Report	Magnitude of the residue of acetamiprid in Winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one decline curve trial in Poland – 2020. Tomasz Peda, 2021, 20SGS12
Guideline(s):	<p>OECD Guidline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>SANCO/825/00, rev. 8.1; 16/11/2010</p> <p>SANCO/3029/99, rev. 4; 11/07/2000</p>
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Methods:

Field trial was established on representative for winter wheat production, grown in a typical way in the test countries. Trial consisted of one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. For untreated and treated plots they consisted of minimum 45m² for decline curve trial. Around the treated and untreated plots a buffer zone (zone where no forbidden products are applied) of at least 10m was set up. The untreated plot was separated by a buffer zone of at least 10 m from treated plot.

The application equipment consisted of boom sprayer.

The foliar applications closely simulated commercial-type treatments.

Calibrations of the spray equipment at the trial site were accomplished by using the volume/time method for liquid applications.

Before each application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

CHR/I/ADEL 200 SE was mixed with water and adjuvant asystent+ (0.1 l/ha) which was added to the spray mixture. The target dose rate of the test item for the study was 0.2 l/ha of formulated product (FP) per application, equivalent to 40 a.s./ha of acetamiprid. Applications were made at a target water volume of 200-300 l/ha of mixture according to good agricultural practice.

Specimen Collection:

Plot number	Specimen Id		Sampling occasion	Specimen type	Minimum sample size	Storage Condition
U	20SGS12-01	1	S1 = 0 DALA*	Whole plant without root	12 units, 0,5 kg	frozen
U	20SGS12-01	1R			12 units, 0,5 kg	frozen
T	20SGS12-01	2			12 units, 0,5 kg	frozen
T	20SGS12-01	2R			12 units, 0,5 kg	frozen
T	20SGS12-01	3	S2 = 7(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS12-01	3R			12 units, 0,5 kg	frozen
T	20SGS12-01	4	S3 = 14(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS12-01	4R			12 units, 0,5 kg	frozen
T	20SGS12-01	5	S4 = 21(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS12-01	5R			12 units, 0,5 kg	frozen
U	20SGS12-01	6	S5 = CH*	Grain	1 kg	frozen
U	20SGS12-01	6R			1 kg	frozen
T	20SGS12-01	7			1 kg	frozen
T	20SGS12-01	7R			1 kg	frozen
U	20SGS12-01	8		Straw	0,5 kg	frozen
U	20SGS12-01	8R			0,5 kg	frozen
T	20SGS12-01	9			0,5 kg	frozen
T	20SGS12-01	9R			0,5 kg	frozen

*CH – Commercial Harvest

*DALA – Days After Last Application

RAC specimens were collected from the central parts of the plots.

Residues concentration detected in analysed field samples:

Plot number	Specimen Id		Sampling occasion	Specimen type	Minimum sample size	Storage Condition
U	20SGS12-01	1	S1 = 0 DALA*	Whole plant without root	12 units, 0,5 kg	frozen
U	20SGS12-01	1R			12 units, 0,5 kg	frozen
T	20SGS12-01	2			12 units, 0,5 kg	frozen
T	20SGS12-01	2R			12 units, 0,5 kg	frozen
T	20SGS12-01	3	S2 = 7(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS12-01	3R			12 units, 0,5 kg	frozen
T	20SGS12-01	4	S3 = 14(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS12-01	4R			12 units, 0,5 kg	frozen
T	20SGS12-01	5	S4 = 21(±1) DALA*	Whole plant without root	12 units, 0,5 kg	frozen
T	20SGS12-01	5R			12 units, 0,5 kg	frozen
U	20SGS12-01	6	S5 = CH*	Grain	1 kg	frozen
U	20SGS12-01	6R			1 kg	frozen
T	20SGS12-01	7			1 kg	frozen
T	20SGS12-01	7R			1 kg	frozen
U	20SGS12-01	8		Straw	0,5 kg	frozen
U	20SGS12-01	8R			0,5 kg	frozen
T	20SGS12-01	9			0,5 kg	frozen
T	20SGS12-01	9R			0,5 kg	frozen

*CH – Commercial Harvest

*DALA – Days After Last Application

RAC specimens were collected from the central parts of the plots.

Blank and fortification samples:

Quality control samples (grain)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0089	89.1
PK1 0,10 mg-kg.lcd	0.10	100.8
PK2 0,010 mg-kg.lcd	0.0090	90.2
PK2 0,10 mg-kg.lcd	0.11	106.6

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Quality control samples (whole plant without root)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0097	96.8
PK1 0,10 mg-kg.lcd	0.11	107.5
PK2 0,010 mg-kg.lcd	0.0097	97.5
PK2 0,10 mg-kg.lcd	0.11	107.3

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Quality control samples (straw)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
PK1 0,010 mg-kg.lcd	0.0088	88.8
PK1 0,10 mg-kg.lcd	0.10	99.7
PK2 0,010 mg-kg.lcd	0.0088	88.1
PK2 0,10 mg-kg.lcd	0.11	107.6

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

This study was fully performed as anticipated, in accordance with the study plan and the amendments issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). Method of determination by LC-MS fulfils the requirements as defined in EC guidance document on residue analytical methods (SANCO/825/00, rev. 8.1. and SANCO/3029/99 rev. 4) and is applicable as enforcement and data generation method for determination of acetamiprid in winter wheat after two applications of CHR/I/ACE 200 SE.

A 2.1.3.1.4 Study 4

Comments of zRMS:	<p>One trial was established in Hungary in 2021. Two applications were performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) + 0.1 l/ha Asystent+ in BBCH 75 (first application) and BBCH 77 (second application). Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.003 mg/kg and 0.01 mg/kg respectively.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid. Residues in grain were below the LOD and at the level of 0.52 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP), two applications instead of one and with the addition of an adjuvant.</p> <p>The study results for grain were used in the evaluation. Max. storage interval between sampling and analysis: about 3 months. Stability studies cover 149 days for grains.</p> <p>Grain: $1 \times < 0.003 \text{ mg/kg}$</p>
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Reference:	KCA 6.3
Report	Magnitude of the residue of acetamiprid in Winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one harvest study in Hungary – 2021. K. Wańczyk, 2021, 20SGS33
Guideline(s):	OECD Guidline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 rev.1, 24/02/2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Methods:

One harvest trial (HS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

Two typical for insecticide applications were performed in trial with boom sprayer on the treated plots at the target dose rate of 0.2 l/ha (CHR/I/ACE 200 SE) + 0.1 l/ha (Asystent+). For the test item CHR/I/ACE 200 SE the reported dose rate was 0,207 L/ha and 0.202 L/ha. For adjuvant Asystent+ the reported dose rate was 0.104 L/ha and 0.101 L/ha.

The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 310 l/ha and 303.3 l/ha.

Foliar applications were performed in BBCH 75 (first application) and BBCH 77 (second application).

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.

Deviations to the target rates were all between $\pm 5\%$ as requested in the study plan (actually it was $+3,5\%$ and $+1\%$).

In harvest trial (HS), RAC specimens for analyses (grain, straw) were collected at: S1 - Commercial Harvest (grain, straw)

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of $-180\text{ }^{\circ}\text{C}$ on the day of sampling, within 12 hours after sampling.

All specimens remained deep frozen during storage at the test site, during shipment to The SGS Polska Sp. z o. o. Environmental Laboratory.

Table 1 Identification of the field trials

Trial number	Study type	EU Zone	Country (region)	Trial site	Zip code
21SGS33-01	HS	North	Hungary (Heves)	Maklar	H-3387

Table 2 Test system information

Trial number	Crop	Variety	Sowing date	Row spacing (cm)	Plant spacing (cm)	Crop density (/ha)	Commercial Harvest Date
21SGS33-01	Winter wheat	Genius	13/10/2020	15,4	1,18	5.500.000 seeds	20.07.2021-23.07.2021

Specimen Collection:

Table 15 Sampling procedures and shipment of RAC specimens

Table 15 Sampling procedures and shipment of RAC specimens													
Specimen number	Plot ID	Actual sampling date	Growth Stage ⁽¹⁾	Sampling event	Actual DALA*	Matrix	Minimum sample size	Weight specimen (g)	Starting time of specimen collection	Time in freezer	Conditions during transport	Target storage temperature (°C)	Shipment date ⁽²⁾
21SGS33-01 1	U	23.07.2021	89	S1	30	Grain	1 kg	1123,91	13:45	19:40	ambient	≤ -18	16.08.2021
21SGS33-01 1R							1 kg	1203,24	13:45	19:40	ambient	≤ -18	-
21SGS33-01 2	U					Straw	0,5 kg	538,56	13:45	19:40	ambient	≤ -18	16.08.2021
21SGS33-01 2R							0,5 kg	506,43	13:45	19:40	ambient	≤ -18	-
21SGS33-01 3	T	23.07.2021	89	S1	30	Grain	1 kg	1109,17	15:20	19:44	ambient	≤ -18	16.08.2021
21SGS33-01 3R							1 kg	1070,40	15:20	19:44	ambient	≤ -18	-
21SGS33-01 4	T					Straw	0,5 kg	639,51	15:20	19:44	ambient	≤ -18	16.08.2021
21SGS33-01 4R							0,5 kg	561,40	15:20	19:44	ambient	≤ -18	-

(1) BBCH – according BBCH stage, See BBCH crop growth scale in appendix D.

(2) Only a part of the specimens were shipped. The other part are spare specimens that were retained deep-frozen, unless required for analysis.

Residues concentration detected in analysed field samples:

Table 10. Residue concentrations of acetamiprid detected in analyzed field samples (Study No.: 21SGS33, Trial No.: 21SGS33-01 Harvest Study)

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	S1 = Commercial Harvest	21SGS33-01 1	wheat (grain)	DPL/03/2021/01U	< LOD
2	S1 = Commercial Harvest	21SGS33-01 2	wheat (straw)	DPL/03/2021/02U	< LOD
3	S1 = Commercial Harvest	21SGS33-01 3	wheat (grain)	DPL/03/2021/03T	< LOD
4	S1 = Commercial Harvest	21SGS33-01 4	wheat (straw)	DPL/03/2021/04T	0.52

*DALA – Days After Last Application, *DBLA- Days Before Last Application
 Residues are not corrected for procedural recoveries;
 Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Blank and fortification samples:

Grain

5 g of the homogenized untreated sample were weighed into a 50 ml centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section 6.2.6 for information on solution preparation), and the sample was extracted as described in 6.2.2.

Table 2. Preparation of fortification and control samples (grain)

Fortification level	Amount of standard solution 1.1 added [µl]	Amount of standard solution 1.2 added [µl]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Straw

2 g of the homogenized untreated sample were weighed into a 50 ml centrifuge tube. Appropriate active substance standard solution was added (see Table 3 for amounts and section 6.2.6 for information on solution preparation), and the sample was extracted as described in 6.2.2.

Table 3. Preparation of fortification and control samples (straw)

Fortification level	Amount of standard solution 1.1 added [µl]	Amount of standard solution 1.2 added [µl]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	20.0
PK 0.10 mg/kg (10xLOQ)	20.0	-

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 20.10.2021 (grain) and 22.10.2021 (straw) and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Conclusion:

The study was conducted using analytical method validated according to SANCO/825/00, rev. 0 and SANCO/3029/99 guidelines. The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for wheat, respectively. The performance of the method during the analytical study complies with SANTE/2020/12830 REV.1 criteria (accuracy in the range 70 -120%). There was no interfering signals at retention time of analysed compound in examined control matrix.

A 2.1.3.1.5 Study 5

Comments of zRMS:	<p>One trial was established in Poland in 2021. Two applications were performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) + 0.1 l/ha Asystent+ in BBCH 75 (first application) and BBCH 77 (second application). Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.003 mg/kg and 0.01 mg/kg respectively.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid. Residues in grain were below the LOD and at the level of 0.066 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP), two applications instead of one and with the addition of an adjuvant.</p> <p>The study results for grain were used in the evaluation. Max. storage interval between sampling and analysis: about 3 months. Stability studies cover 149 days for grains.</p> <p>Grain: $1 \times < 0.003 \text{ mg/kg}$</p>
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Reference:

KCA 6.3

Report

Magnitude of the residue of acetamiprid in Winter wheat (Raw Agricultural Commodity) after two applications of CHR/I/ACE 200 SE with Asystent+ (adjuvant) – one semi decline curve study in Poland – 2021. K. Wańczyk, 2021, 20SGS32

Guideline(s):

OECD Guidline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
 SANCO/825/00, rev. 8.1; 16/11/2010
 SANCO/3029/99, rev. 4; 11/07/2000

Deviations:

No

GLP:

Yes

Acceptability:

Yes

Materials and Methods:

One semi decline curve trial (SDCS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

Two typical for insecticide applications were performed in 'trial with boom sprayer on the treated plots at the target dose rate of 0/2 l/ha (CHR/I/ACE 200 SE) + 0, 1 l/ha (Asystent+). For the test item CHR/I/ACE 200 SE the reported dose rate was 0202 l/ha and 01198 Vha. For adjuvant Asystent+ the reported dose rate was 0, 101 l/ha and 0,099 l/ha. The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 302,7 l/ha and 297,3 l/ha. Foliar applications were performed in BBCH 75 (first application) and BBCH 77 (second application). The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were Verified by the Study Director.

Deviations to the target rates were all between $\pm 5\%$ as requested in the study plan (actually it was $+1\%$ and $-1,0\ 0/0$). In semi decline curve trial (SDCS), RAC specimens for analyses (whole plants without root, grain, straw) were collected at: S1 - 0 Days after application (whole plant without root)
 S2 - Commercial Harvest (grain, straw)

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site. RAC specimens were put in deep freezing conditions at a target temperature of -180 C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test site, during shipment to The SGS Polska Sp. z o. o. Environmental Laboratory

Residues concentration detected in analysed field samples:

Specimen number	Plot ID	Actual sampling date	Growth Stage ⁽¹⁾	Sampling event	Actual DALA*	Matrix	Minimum sample size	Weight specimen (g)	Starting time of specimen collection	Time in freezer	Conditions during transport	Target storage temperature (°C)	Shipment date ⁽²⁾
21SGS32-01 1	U	07.07.2021	77	S1	0	Whole plant w/o roots	1,0 kg 12 units	1156	7:21	9:24	≤ -18	≤ -18	15.09.2021
21SGS32-01 1R								1121	7:21	9:24	≤ -18	≤ -18	-
21SGS32-01 2	T	07.07.2021	77	S1	0	Whole plant w/o roots	1,0 kg 12 units	1232	8:33	9:24	≤ -18	≤ -18	15.09.2021
21SGS32-01 2R								1114	8:33	9:24	≤ -18	≤ -18	-
21SGS32-01 3	U	09.08.2021	89	S2	33	Grain	1,0 kg	1116	16:03	18:47	≤ -18	≤ -18	15.09.2021
21SGS32-01 3R								1076	16:03	18:47	≤ -18	≤ -18	-
21SGS32-01 4	U	09.08.2021	89	S2	33	Straw	0,5 kg	519	16:31	18:47	≤ -18	≤ -18	15.09.2021
21SGS32-01 4R								515	16:31	18:47	≤ -18	≤ -18	-
21SGS32-01 5	T	09.08.2021	89	S2	33	Grain	1,0 kg	1168	16:48	18:47	≤ -18	≤ -18	15.09.2021
21SGS32-01 5R								1048	16:48	18:47	≤ -18	≤ -18	-
21SGS32-01 6	T	09.08.2021	89	S2	33	Straw	0,5 kg	533	17:12	18:47	≤ -18	≤ -18	15.09.2021
21SGS32-01 6R								529	17:12	18:47	≤ -18	≤ -18	-

(1) BBCH – according BBCH stage. See BBCH crop growth scale in appendix D.

(2) Only a part of the specimens were shipped. The other part are spare specimens that were retained deep-frozen, unless required for analysis.

Blank and fortification samples:

Table 11. Quality control samples (grain)

Sample Name	Result [mg/kg]	Recovery [%]
seeds matrix blank.lcd	< LOD	-
seeds PK1 0,01 mg-kg.lcd	0.010	101.3
seeds PK1 0,10 mg-kg.lcd	0.10	100.3
seeds PK2 0,01 mg-kg.lcd	0.010	104.1
seeds PK2 0,10 mg-kg.lcd	0.10	100.8
seeds cal 100 ppb'.lcd	0.10	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Table 12. Quality control samples (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
plant matrix blank.lcd	< LOD	-
plant PK1 0,01 mg-kg.lcd	0.010	101.4
plant PK1 0,10 mg-kg.lcd	0.099	98.7
plant PK2 0,01 mg-kg.lcd	0.0098	97.9
plant PK2 0,10 mg-kg.lcd	0.097	96.6
plant cal 100 ppb'.lcd	0.099	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Table 13. Quality control samples (straw)

Sample Name	Result [mg/kg]	Recovery [%]
straw matrix blank.lcd	< LOD	-
straw PK1 0,01 mg-kg.lcd	0.011	107.2
straw PK1 0,10 mg-kg.lcd	0.11	108.4
straw PK2 0,01 mg-kg.lcd	0.011	108.4
straw PK2 0,10 mg-kg.lcd	0.11	105.5
straw cal 100 ppb'.lcd	0.095	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

This study was fully performed as anticipated, in accordance with the study plan and the amendments issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). Method of determination by LC-MS fulfils the requirements as defined in EC guidance document on residue analytical methods (SANTE/2020/12830 Rev.1)) and is applicable as enforcement and data generation method for determination of acetamiprid in winter wheat after two applications of CHR/I/ACE 200 SE.

zRMS comments:

Comparison of intended and critical EU GAPs for deltamethrin:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (g a.s./ha)	PHI (days)
Wheat (code 0500090)				
cGAP EU EFSA Journal 2015;13(11):4309	n.a.	3 (14 days)	7.5	30
Intended GAP (major use No 3, wheat)	BBCH 37-75	1	4.8	n/a
Intended GAP (major use No 4, triticale)	BBCH 37-75	1	4.8	n/a

Cereals summary for SC formulation (Acetamiprid and Deltamethrin):

Report-No. Location	Commodity	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)		PHI (days)	Remarks
			Kg g.i./ha	Water l/ha	Kg a.i./hl				Acetamiprid	Deltamethrin (sum of cis- Deltamethrin and its alpha-R- isomer and trans- isomer)		
Poland Kolonia Bodzanowska (Kujawsko- Pomorskie) Decline Curve Study Trial 23SGS35-01	Winter wheat Euforia	1 – 29/09/22	0.040 ACE	292.4	0.014	29/06/2023	79	Whole plant w/o root	0.92	0.12	0	The study results for acetamiprid were not used in the evaluation. Max. storage interval between sampling and analysis: 6 months (175
		2 – 03/08/23	0.0049 DEL		0.002			Whole plant w/o root	0.27	0.081	5	
								Whole plant w/o root	0.012	<LOQ	7	

								Whole plant w/o root	0.15	0.20	21	days). Stability studies cover 149 days for acetamiprid in grains. Stability studies for deltamethrin cover storage time. Stability study for acetamiprid covers storage time.
								Grain	<LOQ	<LOD	34	
								Straw	0.26	0.46	34	
Northern France	Winter wheat	1 – 11/10/22	0.041 ACE	253.3	0.016	15/06/2023	77-79	Grain	<LOQ	<LOD	35	The study results were not used in the evaluation.
Auménancourt (Grand-Est)	Volupté	2 – 20/07-30/07/23	0.0049 DEL		0.002			Straw	0.10	0.15	35	Max. storage interval between sampling and analysis for grains: about 6 months (190 days). Stability studies cover 149 days for acetamiprid in grains. Stability studies for deltamethrin cover storage time. Stability study for acetamiprid covers storage time.
Harvest Study Trial 23SGS37-01												
Germany	Winter wheat	1 – 20/10/22	0.040 ACE	298	0.013	22/06/2023	79	Whole plant w/o root	0.77	0.095	0	The study results were not used in the evaluation.
Herzberg (Mark)	RGT Reform	2 – 16/07/-23/07/23										

(Brandenburg) Decline Curve Study Trial 23SGS38-01								Whole plant w/o root	0.74	0.068	5	Max. storage interval between sampling and analysis for grains: about 6 months (192 days). Stability studies for acetamiprid cover 149 days for grains. Stability studies for deltamethrin cover storage time Stability study for acetamiprid covers storage time.
			0.0048 DEL		0.002			Whole plant w/o root	0.068	0.065	7	
								Whole plant w/o root	0.095	0.088	21	
								Grain	<LOQ	<LOQ	34	
								Straw	0.086	0.10	34	
Hungary Monok (Borsod-Abaúj- Zemplén) Harvest Study Trial 23SGS39-01	Winter wheat Basilio	1 – 28/09/22 2 – 17/07-18/07/23	0.0439 ACE	290	0.015	19/06/2023	79	Grain	<LOQ	<LOD	28	The study results were not used in the evaluation. Max. storage interval between sampling and analysis for grains: about 6 months (193 days). Stability studies for acetamiprid cover 149 days for grains. Stability studies for deltamethrin cover storage time Stability study
			0.0047 DEL		0.016			Straw	0.076	0.16	28	

												for acetamiprid covers storage time.
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A 2.1.3.1.6 Study 6

Comments of zRMS:	<p>The study is accepted.</p> <p>One decline study trial was established in Poland in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid /ha and 4.8 g/ha deltamethrin) in BBCH 79.</p> <p><u>Acetamiprid</u></p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.001 mg/kg for plant and grain, 0.0015 mg/kg for straw and 0.005 mg/kg for grain, plant and straw respectively.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for all plant products was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Residues in grain were 0.0053 mg/kg and 0.26 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens. It should be noted that the results indicated below by the Applicant differ slightly from the results indicated in the study report, were only results below the LOQ are in the grain.</p> <p>The study results were not used in the evaluation. Max. storage interval between sampling and analysis for grains: about 6 months (175 days). Stability studies cover 149 days for grains. Stability study for acetamiprid covers storage time.</p> <p><u>Deltamethrin</u></p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (plant, grain, strain). The limit of detection for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in grain and plant was 0.002 mg/kg and 0.0025 mg/kg for straw.</p> <p>Residues in grain were below LOD and 0.46 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens. Stability studies for deltamethrin cover storage time.</p>
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Reference:

KCA 6.3

Report

Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one decline curve study trial in Poland – 2023, Peda, T., Głowiak, K. , 2024, 23SGS35

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the

Design, Preparation and Realization of Residue Trials, July 22, 1997

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and Methods:

The objective of the study was to determine the residue level for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin,

Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat RAC specimens in one decline curve study trial following one application of the formulated product

CHR/I/ADEL 280 SC under cultural practice typical for winter wheat production.

Decline curve study (DCS) trial was established in Poland. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g acetamiprid and 4,8 g deltamethrin.

Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,156 l/ha (292,4 l/ha water).

Application was performed at BBCH 79.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -2,5%.

RAC specimens for analyses were collected:

- S1 (Whole plant without root) – 0 DALA
- S2 (Whole plant without root) – 5 DALA
- S3 (Whole plant without root) – 7 DALA
- S4 (Whole plant without root) - 21(±1) DALA
- S5 (Grain, Straw) – CH

Residues concentration detected in analysed field samples:

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]						
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl ^a	Cis-deltamethrin	Trans-deltamethrin	Alpha-R-deltamethrin	deltamethrin (sum of cis-Deltamethrin and its alpha-R-isomer and trans-isomer)
1	0 DALA	23SGS35-01 1	wheat (whole plant without root)	DPL/77/2023/01U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
2		23SGS35-01 2	wheat (whole plant without root)	DPL/77/2023/02T	0.92	0.019	0.94	0.12	<LOD	<LOD	0.12
3	5 DALA	23SGS35-01 3	wheat (whole plant without root)	DPL/77/2023/03T	0.27	0.12	0.40	0.081	<LOQ	<LOD	0.081
4	7 DALA	23SGS35-01 4	wheat (whole plant without root)	DPL/77/2023/04T	0.012	0.011	0.024	<LOQ	<LOD	<LOD	<LOD
5	21(±1) DALA	23SGS35-01 5	wheat (whole plant without root)	DPL/77/2023/05T	0.15	0.10	0.26	0.19	0.014	<LOQ	0.20
6	CH	23SGS35-01 6	wheat (grain)	DPL/77/2023/06U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
7		23SGS35-01 7	wheat (straw)	DPL/77/2023/07U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
8		23SGS35-01 8	wheat (grain)	DPL/77/2023/08T	0.0053	0.0076	0.013	<LOD	<LOD	<LOD	<LOD
9		23SGS35-01 9	wheat (straw)	DPL/77/2023/09T	0.26	0.12	0.39	0.42	0.024	0.017	0.46

sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

DALA-Days After Last Application; CH-Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values,

.LOD = 0.001 mg/kg (grain, plant)/ 0.0015 (straw) for acetamiprid; = 0.001 mg/kg (grain, plant)/ 0.0015 (straw) for acetamiprid-N-desmethyl

.LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl; LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

.LOD= 0.002 mg/kg (grain, plant)/ 0.0025 (straw), LOQ = 0.010 mg/kg for deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer)

Blank and fortification samples:

7.2.1 WHEAT PLANT

7.2.1.1 Analysis of samples 25.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat plant:

Acetamiprid

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant sample blank.lcd	<LOD	-
plant PK1 0,005 mg-kg.lcd	0.0050	99.3
plant PK1 0,05 mg-kg.lcd	0.052	103.5
plant PK2 0,005 mg-kg.lcd	0.0052	104.5
plant PK2 0,05 mg-kg.lcd	0.053	106.4

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant sample blank.lcd	<LOD	-
plant PK1 0,005 mg-kq.lcd	0.0045	89.2
plant PK1 0,05 mg-kq.lcd	0.050	100.4
plant PK2 0,005 mg-kq.lcd	0.0040	79.8
plant PK2 0,05 mg-kq.lcd	0.049	98.1

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

- 7.2.1.2 Analysis of samples 25.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer) in wheat plant:

Cis - Deltamethrin

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant, sample blank	<LOD	-
plant, PK1 0,010 mg-kq	0.0098	98.3
plant, PK1 0,10 mg-kq	0.10	103.2
plant, PK2 0,010 mg-kq	0.0095	94.9
plant, PK2 0,10 mg-kq	0.10	99.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin trans isomer

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant, sample blank	<LOD	-
plant, PK1 0,010 mg-kg	0.0097	96.9
plant, PK1 0,10 mg-kg	0.10	103.1
plant, PK2 0,010 mg-kg	0.0095	95.3
plant, PK2 0,10 mg-kg	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin alpha R isomer

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant, sample blank	<LOD	-
plant, PK1 0,010 mg-kg	0.0094	94.1
plant, PK1 0,10 mg-kg	0.096	96.3
plant, PK2 0,010 mg-kg	0.010	103.9
plant, PK2 0,10 mg-kg	0.094	93.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

7.2.2 WHEAT GRAIN

7.2.2.1 Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat grain:

Acetamiprid

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0048	95.9
grain PK1 0,05 mg-kg.lcd	0.051	102.4
grain PK2 0,005 mg-kg.lcd	0.0053	105.4
grain PK2 0,05 mg-kg.lcd	0.051	102.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0046	91.6
grain PK1 0,05 mg-kg.lcd	0.054	107.6
grain PK2 0,005 mg-kg.lcd	0.0047	94.1
grain PK2 0,05 mg-kg.lcd	0.052	104.0

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Cis - Deltamethrin

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	99.9
grain, PK1 0,10 mg-kg	0.10	101.6
grain, PK2 0,010 mg-kg	0.011	107.7
grain, PK2 0,10 mg-kg	0.10	103.7

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin trans isomer

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	105.0
grain, PK1 0,10 mg-kg	0.10	102.1
grain, PK2 0,010 mg-kg	0.011	107.2
grain, PK2 0,10 mg-kg	0.11	105.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin alpha R isomer

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	100.6
grain, PK1 0,10 mg-kg	0.10	101.5
grain, PK2 0,010 mg-kg	0.012	116.9
grain, PK2 0,10 mg-kg	0.11	109.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

WHEAT STRAW

Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat straw:

Acetamiprid

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0050	100.0
straw PK1 0,05 mg-kg.lcd	0.046	92.3
straw PK2 0,005 mg-kg.lcd	0.0048	95.1
straw PK2 0,05 mg-kg.lcd	0.052	103.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0054	108.0
straw PK1 0,05 mg-kg.lcd	0.048	96.9
straw PK2 0,005 mg-kg.lcd	0.0059	117.7
straw PK2 0,05 mg-kg.lcd	0.050	100.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

- 3.2 Analysis of samples 26.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer):

Cis - Deltamethrin

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kg	0.0088	87.9
straw, PK1 0,10 mg-kg	0.10	100.0
straw, PK2 0,010 mg-kg	0.0089	89.0
straw, PK2 0,10 mg-kg	0.10	102.2

LOD = 0.0025 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin trans isomer

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kg	0.0088	87.7
straw, PK1 0,10 mg-kg	0.10	99.8
straw, PK2 0,010 mg-kg	0.0090	90.1
straw, PK2 0,10 mg-kg	0.099	99.2

LOD = 0.0025 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin alpha R isomer

Table 31. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kg	0.011	106.4
straw, PK1 0,10 mg-kg	0.11	106.9
straw, PK2 0,010 mg-kg	0.011	108.8
straw, PK2 0,10 mg-kg	0.12	115.7

LOD = 0.0025 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023
The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.010 mg/kg for wheat (plant, grain, straw). The limit of quantification of the method was established at 0.010 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (plant, grain, straw).
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70–120%).
There were no interfering signals at retention time of analyzed compound in examined control matrix.

A 2.1.3.1.7 Study 7

Comments of zRMS:	<p>The study is accepted.</p> <p>One trial was established in Northern France in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid /ha and 4.8 g/ha deltamethrin) in BBCH 77-79.</p> <p>Acetamiprid</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) and quantification (LOQ) of the analytical method for wheat was 0.001 mg/kg for plant and grain, 0.0015 mg/kg for straw and 0.005 mg/kg for grain, plant and straw respectively.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for all plant products was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Residues in grain were below LOQ and were at the level of 0.1 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study results were not used in the evaluation. Max. storage interval between sampling and analysis for grains: about 6 months (190 days). Stability studies cover 149 days for grains. Stability study for acetamiprid covers storage time.</p> <p>Deltamethrin</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (plant, grain, strain). The limit of detection for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in grain and plant was 0.002 mg/kg and 0.0025 mg/kg for straw.</p> <p>Residues in grain were below LOD and 0.15 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>Stability studies for deltamethrin cover storage time.</p>
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Reference:

KCA 6.3

Report

Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one harvest study trial in Northern France – 2023, Peda, T., Głowiak, K., 2024, 23SGS37

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and Methods:

The objective of the study was to determine the residue level for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin,

Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat RAC specimens in one harvest study trial following one application of the formulated product

CHR/I/ADEL 280 SC under cultural practice typical for winter wheat production.

Harvest study (HS) trial was established in Northern France. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g acetamiprid and 4,8 g deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,162 l/ha (253,3 l/ha water).

Application was performed at BBCH 77-79.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was +1,3%.

RAC specimens for analyses were collected:

- S1 (Grain, Straw) – CH

Residues concentration detected in analysed field samples:

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]						
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*	Cis-deltamethrin	Trans-deltamethrin	Alpha-R-deltamethrin	deltamethrin (sum of cis-Deltamethrin and its alpha-R-isomer and trans-isomer)
1	BBCH 89 / CH	23SGS37-01 1	wheat (grain)	DPL/104/2023/01U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
2		23SGS37-01 2	wheat (straw)	DPL/104/2023/02U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
3		23SGS37-01 3	wheat (grain)	DPL/104/2023/03T	<LOQ	<LOQ	<LOQ	<LOD	<LOD	<LOD	<LOD
4		23SGS37-01 4	wheat (straw)	DPL/104/2023/04T	0.10	0.050	0.15	0.13	0.013	0.011	0.15

* sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

DALA-Days After Last Application; CH-Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values.

LOD = 0.001 mg/kg (grain)/ 0.0015 (straw) for acetamiprid; LOD = 0.001 mg/kg (grain)/ 0.0015 (straw) for acetamiprid-N-desmethyl

LOQ = 0.005 mg/kg for acetamiprid; LOQ = 0.005 mg/kg for acetamiprid-N-desmethyl; LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

LOD= 0.002 mg/kg (grain)/ 0.0025 (straw), LOQ = 0.010 mg/kg for deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer)

Blank and fortification samples:

7.2.1 WHEAT GRAIN

7.2.1.1 Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat grain:

Acetamiprid

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0048	95.9
grain PK1 0,05 mg-kg.lcd	0.051	102.4
grain PK2 0,005 mg-kg.lcd	0.0053	105.4
grain PK2 0,05 mg-kg.lcd	0.051	102.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0046	91.6
grain PK1 0,05 mg-kg.lcd	0.054	107.6
grain PK2 0,005 mg-kg.lcd	0.0047	94.1
grain PK2 0,05 mg-kg.lcd	0.052	104.0

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

- I.2 Analysis of samples 26.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer) in wheat grain:

Cis - Deltamethrin

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	99.9
grain, PK1 0,10 mg-kg	0.10	101.6
grain, PK2 0,010 mg-kg	0.011	107.7
grain, PK2 0,10 mg-kg	0.10	103.7

LOD = 0.002 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin trans isomer

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg/kg	0.010	105.0
grain, PK1 0,10 mg/kg	0.10	102.1
grain, PK2 0,010 mg/kg	0.011	107.2
grain, PK2 0,10 mg/kg	0.11	105.5

LOD = 0.002 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin alpha R isomer

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg/kg	0.010	100.6
grain, PK1 0,10 mg/kg	0.10	101.5
grain, PK2 0,010 mg/kg	0.012	116.9
grain, PK2 0,10 mg/kg	0.11	109.1

LOD = 0.002 mg/kg, LOQ = 0.01 mg/kg

7.2.2 WHEAT STRAW

7.2.2.1 Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat straw:

Acetamiprid

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0050	100.0
straw PK1 0,05 mg-kg.lcd	0.046	92.3
straw PK2 0,005 mg-kg.lcd	0.0048	95.1
straw PK2 0,05 mg-kg.lcd	0.052	103.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0054	108.0
straw PK1 0,05 mg-kg.lcd	0.048	96.9
straw PK2 0,005 mg-kg.lcd	0.0059	117.7
straw PK2 0,05 mg-kg.lcd	0.050	100.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

Cis - Deltamethrin

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kg	0.0088	87.9
straw, PK1 0,10 mg-kg	0.10	100.0
straw, PK2 0,010 mg-kg	0.0089	89.0
straw, PK2 0,10 mg-kg	0.10	102.2

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin trans isomer

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kg	0.0088	87.7
straw, PK1 0,10 mg-kg	0.10	99.8
straw, PK2 0,010 mg-kg	0.0090	90.1
straw, PK2 0,10 mg-kg	0.099	99.2

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kg	0.011	106.4
straw, PK1 0,10 mg-kg	0.11	106.9
straw, PK2 0,010 mg-kg	0.011	108.8
straw, PK2 0,10 mg-kg	0.12	115.7

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023
 The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl, and for “sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid” limit of quantification was 0.010 mg/kg for wheat (grain, straw). The limit of quantification of the method was established at 0.010 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (grain, straw).
 The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70–120%).
 There were no interfering signals at retention time of analyzed compound in examined control matrix.

A 2.1.3.1.8 Study 8

Comments of zRMS:	<p>The study is accepted.</p> <p>One decline study trial was established in Germany in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid /ha and 4.8 g/ha deltamethrin) in BBCH 79.</p> <p>Acetamiprid Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of detection (LOD) of the analytical method for wheat was 0.001 mg/kg for plant and grain, 0.0015 mg/kg for straw; limit of quantification (LOQ) was 0.005 mg/kg for wheat grain, plant and straw. Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for all plant products was establish as acetamiprid only, the acetamiprid results were used for further evaluation. Residues in grain were below LOQ and at the level of 0.086 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study results were not used in the evaluation. Max. storage interval between sampling and analysis for grains: about 6 months (192 days). Stability studies cover 149 days for grains. Stability study for acetamiprid covers storage time.</p> <p>Deltamethrin Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (plant, grain, strain). The limit of detection for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in grain and plant was 0.002 mg/kg and 0.0025 mg/kg for straw. Residues in grain were below LOQ and 0.10 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens. Stability studies for deltamethrin cover storage time.</p>
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Reference:

KCA 6.3

Report

Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid

(IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one decline curve study trial in Germany – 2023, Peda, T., Głowiak, K. , 2024, 23SGS38

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations:

No

GLP:

Yes

Acceptability:

Yes

Materials and Methods:

The objective of the study was to determine the residue level for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat RAC specimens in one decline curve study trial following one application of the formulated product CHR/I/ADEL 280 SC under cultural practice typical for winter wheat production.

Decline curve study (DCS) trial was established in Germany. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g acetamiprid and 4,8 g deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,159 l/ha (298 l/ha water).

Application was performed at BBCH 79.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -0,6%.

RAC specimens for analyses were collected:

- S1 (Whole plant without root) – 0 DALA
- S2 (Whole plant without root) – 5 DALA
- S3 (Whole plant without root) – 7 DALA
- S4 (Whole plant without root) - 21(±1) DALA
- S5 (Grain, Straw) – CH

Residues concentration detected in analysed field samples:

Residues concentration detected in analysed field samples:

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]						
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*	Cis-deltamethrin	Trans-deltamethrin	Alpha-R-deltamethrin	deltamethrin (sum of cis-Deltamethrin and its alpha-R-isomer and trans-isomer)
1	0 DALA	23SGS38-01 1	wheat (whole plant without root)	DPL/105/2023/01U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
2		23SGS38-01 2	wheat (whole plant without root)	DPL/105/2023/02T	0.77	<LOQ	0.77	0.095	<LOD	<LOD	0.095
3	5 DALA	23SGS38-01 3	wheat (whole plant without root)	DPL/105/2023/03T	0.074	0.035	0.11	0.068	<LOD	<LOD	0.068
4	7 DALA	23SGS38-01 4	wheat (whole plant without root)	DPL/105/2023/04T	0.068	0.033	0.10	0.065	<LOQ	<LOD	0.065
5	21(±1) DALA	23SGS38-01 5	wheat (whole plant without root)	DPL/105/2023/05T	0.095	0.041	0.14	0.088	<LOQ	<LOD	0.088
6	CH	23SGS38-01 6	wheat (grain)	DPL/105/2023/06U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
7		23SGS38-01 7	wheat (straw)	DPL/105/2023/07U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
8		23SGS38-01 8	wheat (grain)	DPL/105/2023/08T	<LOQ	0.0054	<LOQ (0.0054)	<LOQ	<LOD	<LOD	<LOQ
9		23SGS38-01 9	wheat (straw)	DPL/105/2023/09T	0.086	0.054	0.14	0.10	<LOQ	<LOD	0.10

*sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

DALA-Days After Las Application; CH-Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values,

LOD = 0.001 mg/kg (grain, plant)/ 0.0015 (straw) for acetamiprid; LOD = 0.001 mg/kg (grain, plant)/ 0.0015 (straw) for acetamiprid-N-desmethyl

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl; LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

LOD= 0.002 mg/kg (grain, plant)/ 0.0025 (straw), LOQ = 0.010 mg/kg for deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer)

Blank and fortification samples:

Acetamiprid

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant sample blank.lcd	<LOD	-
plant PK1 0,005 mg-kg.lcd	0.0050	99.3
plant PK1 0,05 mg-kg.lcd	0.052	103.5
plant PK2 0,005 mg-kg.lcd	0.0052	104.5
plant PK2 0,05 mg-kg.lcd	0.053	106.4

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant sample blank.lcd	<LOD	-
plant PK1 0,005 mg-kg.lcd	0.0045	89.2
plant PK1 0,05 mg-kg.lcd	0.050	100.4
plant PK2 0,005 mg-kg.lcd	0.0040	79.8
plant PK2 0,05 mg-kg.lcd	0.049	98.1

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

2. Analysis of samples 25.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer) in wheat plant:

Cis - Deltamethrin

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant, sample blank	<LOD	-
plant, PK1 0,010 mg-kg	0.0098	98.3
plant, PK1 0,10 mg-kg	0.10	103.2
plant, PK2 0,010 mg-kg	0.0095	94.9
plant, PK2 0,10 mg-kg	0.10	99.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin trans isomer

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant, sample blank	<LOD	-
plant, PK1 0,010 mg-kg	0.0097	96.9
plant, PK1 0,10 mg-kg	0.10	103.1
plant, PK2 0,010 mg-kg	0.0095	95.3
plant, PK2 0,10 mg-kg	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin alpha R isomer

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
plant, sample blank	<LOD	-
plant, PK1 0,010 mg-kg	0.0094	94.1
plant, PK1 0,10 mg-kg	0.096	96.3
plant, PK2 0,010 mg-kg	0.010	103.9
plant, PK2 0,10 mg-kg	0.094	93.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

WHEAT GRAIN

Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat grain:

Acetamiprid

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0048	95.9
grain PK1 0,05 mg-kg.lcd	0.051	102.4
grain PK2 0,005 mg-kg.lcd	0.0053	105.4
grain PK2 0,05 mg-kg.lcd	0.051	102.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0046	91.6
grain PK1 0,05 mg-kg.lcd	0.054	107.6
grain PK2 0,005 mg-kg.lcd	0.0047	94.1
grain PK2 0,05 mg-kg.lcd	0.052	104.0

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

- 2 Analysis of samples 26.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and isomer) in wheat grain:

Cis - Deltamethrin

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	99.9
grain, PK1 0,10 mg-kg	0.10	101.6
grain, PK2 0,010 mg-kg	0.011	107.7
grain, PK2 0,10 mg-kg	0.10	103.7

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin trans isomer

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	105.0
grain, PK1 0,10 mg-kg	0.10	102.1
grain, PK2 0,010 mg-kg	0.011	107.2
grain, PK2 0,10 mg-kg	0.11	105.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	100.6
grain, PK1 0,10 mg-kg	0.10	101.5
grain, PK2 0,010 mg-kg	0.012	116.9
grain, PK2 0,10 mg-kg	0.11	109.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

.3 WHEAT STRAW

3.1 Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat straw:

Acetamiprid

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0050	100.0
straw PK1 0,05 mg-kg.lcd	0.046	92.3
straw PK2 0,005 mg-kg.lcd	0.0048	95.1
straw PK2 0,05 mg-kg.lcd	0.052	103.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kq.lcd	0.0054	108.0
straw PK1 0,05 mg-kq.lcd	0.048	96.9
straw PK2 0,005 mg-kq.lcd	0.0059	117.7
straw PK2 0,05 mg-kq.lcd	0.050	100.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

- 3.2 Analysis of samples 28.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer):

Cis - Deltamethrin

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg-kq	0.0088	87.9
straw, PK1 0,10 mg-kq	0.10	100.0
straw, PK2 0,010 mg-kq	0.0089	89.0
straw, PK2 0,10 mg-kq	0.10	102.2

LOD = 0.0025 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin trans isomer

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg/kg	0.0088	87.7
straw, PK1 0,10 mg/kg	0.10	99.8
straw, PK2 0,010 mg/kg	0.0090	90.1
straw, PK2 0,10 mg/kg	0.099	99.2

LOD = 0.0025 mg/kg, LOQ = 0.010 mg/kg

Deltamethrin alpha R isomer

Table 31. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg/kg	0.011	106.4
straw, PK1 0,10 mg/kg	0.11	106.9
straw, PK2 0,010 mg/kg	0.011	108.8
straw, PK2 0,10 mg/kg	0.12	115.7

LOD = 0.0025 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023
 The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.010 mg/kg for wheat (plant, grain, straw). The limit of quantification of the method was established at 0.010 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (plant, grain, straw).
 The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70–120%).
 There were no interfering signals at retention time of analyzed compound in examined control matrix.

A 2.1.3.1.9 Study 9

Comments of zRMS:	<p>The study is accepted.</p> <p>One decline study trial was established in Hungary in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid /ha and 4.8 g/ha deltamethrin) in BBCH 79.</p> <p><u>Acetamiprid</u></p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of detection (LOD) of the analytical method for wheat was 0.001 mg/kg for plant and grain, 0.0015 mg/kg for straw; limit of quantification (LOQ) was 0.005 mg/kg for wheat grain, plant and straw.</p> <p>Grain, straw and whole plant samples of treated and untreated wheat from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for all plant products was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Residues in grain were below LOQ and at the level of 0.076 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens.</p> <p>The study results were not used in the evaluation. Max. storage interval between sampling and analysis for grains: about 6 months (193 days). Stability studies cover 149 days for grains. Stability study for acetamiprid covers storage time.</p> <p><u>Deltamethrin</u></p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure). The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (plant, grain, strain). The limit of detection for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in grain and plant was 0.002 mg/kg and 0.0025 mg/kg for straw.</p> <p>Residues in grain were below LOD and 0.16 mg/kg in straw. No residues above the LOD were detected in any of the untreated specimens. Stability studies for deltamethrin cover storage time.</p>
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Reference:	KCA 6.3
Report	Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one harvest study trial in Hungary – 2023, Peda, T., Niewelt-Stasiak, S., 2024, 23SGS39
Guideline(s):	<p>Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997</p> <p>OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509</p>

published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and Methods:

The objective of the study was to determine the residue level for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid and sum of Deltamethrin.

Trans-deltamethrin and alpha-R-isomer of deltamethrin in winter wheat RAC specimens in one harvest study trial following one application of the formulated product

CHR/I/ADEL 280 SC under cultural practice typical for winter wheat production.

Harvest study (HS) trial was established in Hungary. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g acetamiprid and 4,8 g deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,155 l/ha (290 l/ha water).

Application was performed at BBCH 79.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -3,3%.

RAC specimens for analyses were collected:

- S1 (Grain, Straw) – CH

Residues concentration detected in analysed field samples:

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]						
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*	Cis-deltamethrin	Trans-deltamethrin	Alpha-R-deltamethrin	deltamethrin (sum of cis-Deltamethrin and its alpha-R-isomer and trans-isomer)
1	BBCH 89 / CH	23SGS39-01 1	wheat (grain)	DPL/88/2023/01U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
2		23SGS39-01 2	wheat (straw)	DPL/88/2023/02U	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOQ
3		23SGS39-01 3	wheat (grain)	DPL/88/2023/03T	<LOQ	<LOQ	<LOQ	<LOD	<LOD	<LOD	<LOD
4		23SGS39-01 4	wheat (straw)	DPL/88/2023/04T	0.076	0.052	0.13	0.13	<LOQ	0.031	0.16

* sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

DALA-Days After Last Application; CH-Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values.

LOD = 0.001 mg/kg (grain)/ 0.0015 (straw) for acetamiprid; LOD = 0.001 mg/kg (grain)/ 0.0015 (straw) for acetamiprid-N-desmethyl

LOQ = 0.005 mg/kg for acetamiprid; LOQ = 0.005 mg/kg for acetamiprid-N-desmethyl; LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

LOD= 0.002 mg/kg (grain)/ 0.0025 (straw), LOQ = 0.010 mg/kg for deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer)

Blank and fortification samples:

7.2.1 WHEAT GRAIN

7.2.1.1 Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat grain:

Acetamiprid

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0048	95.9
grain PK1 0,05 mg-kg.lcd	0.051	102.4
grain PK2 0,005 mg-kg.lcd	0.0053	105.4
grain PK2 0,05 mg-kg.lcd	0.051	102.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain sample blank.lcd	<LOD	-
grain PK1 0,005 mg-kg.lcd	0.0046	91.6
grain PK1 0,05 mg-kg.lcd	0.054	107.6
grain PK2 0,005 mg-kg.lcd	0.0047	94.1
grain PK2 0,05 mg-kg.lcd	0.052	104.0

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

- 2 Analysis of samples 26.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer) in wheat grain:

Cis - Deltamethrin

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	99.9
grain, PK1 0,10 mg-kg	0.10	101.6
grain, PK2 0,010 mg-kg	0.011	107.7
grain, PK2 0,10 mg-kg	0.10	103.7

LOD = 0.002 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin trans isomer

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	105.0
grain, PK1 0,10 mg-kg	0.10	102.1
grain, PK2 0,010 mg-kg	0.011	107.2
grain, PK2 0,10 mg-kg	0.11	105.5

LOD = 0.002 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin alpha R isomer

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
grain, sample blank	<LOD	-
grain, PK1 0,010 mg-kg	0.010	100.6
grain, PK1 0,10 mg-kg	0.10	101.5
grain, PK2 0,010 mg-kg	0.012	116.9
grain, PK2 0,10 mg-kg	0.11	109.1

LOD = 0.002 mg/kg, LOQ = 0.01 mg/kg

WHEAT STRAW

Analysis of samples 26.01.2024 – acetamiprid and acetamiprid-N-desmethyl in wheat straw:

Acetamiprid

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0050	100.0
straw PK1 0,05 mg-kg.lcd	0.046	92.3
straw PK2 0,005 mg-kg.lcd	0.0048	95.1
straw PK2 0,05 mg-kg.lcd	0.052	103.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

Acetamiprid-N-desmethyl

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw sample blank.lcd	<LOD	-
straw PK1 0,005 mg-kg.lcd	0.0054	108.0
straw PK1 0,05 mg-kg.lcd	0.048	96.9
straw PK2 0,005 mg-kg.lcd	0.0059	117.7
straw PK2 0,05 mg-kg.lcd	0.050	100.9

LOD = 0.0015 mg/kg, LOQ = 0.005 mg/kg

Analysis of samples 26.01.2024 – Deltamethrin (cis-Deltamethrin and its alpha-R-isomer and trans-isomer):

Cis - Deltamethrin

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg/kg	0.0088	87.9
straw, PK1 0,10 mg/kg	0.10	100.0
straw, PK2 0,010 mg/kg	0.0089	89.0
straw, PK2 0,10 mg/kg	0.10	102.2

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin trans isomer

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg/kg	0.0088	87.7
straw, PK1 0,10 mg/kg	0.10	99.8
straw, PK2 0,010 mg/kg	0.0090	90.1
straw, PK2 0,10 mg/kg	0.099	99.2

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

Deltamethrin alpha R isomer

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
straw, sample blank	<LOD	-
straw, PK1 0,010 mg/kg	0.011	106.4
straw, PK1 0,10 mg/kg	0.11	106.9
straw, PK2 0,010 mg/kg	0.011	108.8
straw, PK2 0,10 mg/kg	0.12	115.7

LOD = 0.0025 mg/kg, LOQ = 0.01 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023

The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl, and for “sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid” limit of quantification was 0.010 mg/kg for wheat (grain, straw). The limit of quantification of the method was established at 0.010 mg/kg for deltamethrin (cis-deltamethrin and its alpha-R-isomer and trans-isomer) in wheat (grain, straw).

The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70–120%).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

A 2.1.3.2 Sugar beet (acetamiprid)

Sugar beet summary for SE formulation:

Report-No. Location	Commodity	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i/ha	Water l/ha	Kg a.i./hl						
20SGS29, Poland, Dolnośląskie	Sugar beet	1) 09.05.2020 2) 06.10.2020	0.041	307.1	0.0134	01.07.2020	BBCH 19	Leaves	<0.003	66	LOQ=0.01 mg/kg LOD: 0.003 mg/kg
								Roots	<0.003		
21SGS26, Germany, Branderburg, Stoofin	Sugar beet	1) 15.04.2021 2) 23.08.2021- 19.09.2021	0.03912	293.3	0.0133	10.06.2021	BBCH 19	Leaves	<0.003	95	LOQ=0.01 mg/kg LOD: 0.003 mg/kg
								Roots	<0.003		
21SGS27, France, Ground-East, Aumenancourt	Sugar beet	1) 26.03.2021 2) 01.09.2021- 02.09.2021	0.0392	343.3	0.0114	10.06.2021	BBCH 19	Leaves	<0.01	84	LOQ=0.01 mg/kg LOD: 0.003 mg/kg
								Roots	<0.003		

20SGS30 Poland Miastowice, Northern zone, 2020	Sugar beet/ Jaromir	1. 2.05.2020 2. – 3. 20.10.2020 3)	0.0404	302.9	0.0134	16.06.2020	BBCH 19	Leaves	≤LOQ < 0.003		LOQ=0.01 mg.kg LOD: 0.003 mg/kg
								Roots	≤LOQ < 0.003		

zRMS comments:

Comparison of intended and critical EU GAPs:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (kg a.s./ha)	PHI (days)
Sugar beet roots (code 0900010)				
GAP EU	-	-	-	-
Intended GAP (major use No 5)	BBCH 12-19	1	0.04	n/a

A 2.1.3.2.1 Study 1

Comments of zRMS:	<p>One semi decline study trial was established in Poland in 2020 (trial site Miastowice, zip code 88-240). One application was performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) in BBCH 19.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP). The Applicant provided bridging studies. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of detection (LOD) of the analytical method was 0.003 mg/kg; limit of quantification (LOQ) was 0.01 mg/kg.</p> <p>Sugar beet roots and leaves samples from the field trials were analysed for residues of acetamiprid. Residues in all analysed samples were below LOD.</p> <p>Max. storage interval between sampling and analysis: about 2 months. Stability studies cover 12 months for high water matrices.</p> <p>The study is accepted.</p> <p>The study results used in the evaluation: sugar beet, roots: $1 \times < 0.003 \text{ mg/kg}$ sugar beet, leaves: $1 \times < 0.003 \text{ mg/kg}$</p>
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Reference:	KCA 6.3
Report	Magnitude of the residue of acetamiprid in Sugar beet (Raw Agricultural Commodity) after one applications of CHR/I/ACE 200 SE one semi decline curve trial in Poland – 2020. Tomasz Peda, 2021, 20SGS30
Guideline(s):	OECD Guideline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANCO/825/00, rev. 8.1; 16/11/2010 SANCO/3029/99, rev. 4; 11/07/2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Methods:

Field trial was established on sugar beet production, grown in a typical way in the test country. Trial consisted of one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. For untreated and treated plots they consisted of minimum 45m² for semi decline curve study. Around the treated and untreated plots a buffer zone (zone where no forbidden products are applied) of at least 10m was set up. The untreated plot was separated by a buffer zone of at least 10 m from treated plot.

The application equipment consisted of boom sprayer.

The foliar applications closely simulated commercial-type treatments.

Calibrations of the spray equipment at the trial site were accomplished by using the volume/time method for liquid applications.

Before each application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

CHR/I/ADEL 200 SE was mixed with water , no adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 0.2 l/ha of formulated product (FP) per application, equivalent to 40 a.s./ha of acetamiprid. Applications were made at a target water volume of 300-400 l/ha of mixture according to good agricultural practice.

Specimen collection:

Trial number: 20SGS30-01

Plot number	Specimen Id		Sampling occasion	Specimen type	Minimum sample size	Storage Condition
U	20SGS30-01	1	S1 = 14(±1)DBH	Leaves	12 units; 1 kg	frozen
U	20SGS30-01	1R			12 units; 1 kg	frozen
U	20SGS30-01	2		Roots	12 units; 1 kg	frozen
U	20SGS30-01	2R			12 units; 1 kg	frozen
T	20SGS30-01	3		Leaves	12 units; 1 kg	frozen
T	20SGS30-01	3R			12 units; 1 kg	frozen
T	20SGS30-01	4		Roots	12 units; 1 kg	frozen
T	20SGS30-01	4R			12 units; 1 kg	frozen
U	20SGS30-01	5	S2 = BBCH 49	Leaves	12 units; 1 kg	frozen
U	20SGS30-01	5R			12 units; 1 kg	frozen
U	20SGS30-01	6		Roots	12 units; 1 kg	frozen
U	20SGS30-01	6R			12 units; 1 kg	frozen
T	20SGS30-01	7		Leaves	12 units; 1 kg	frozen
T	20SGS30-01	7R			12 units; 1 kg	frozen
T	20SGS30-01	8		Roots	12 units; 1 kg	frozen
T	20SGS30-01	8R			12 units; 1 kg	frozen

*DBH – Days Before Harvest

Residues concentration detected in analysed field samples:

Trial 20SGS30-01

Sample name	Timing	Type of commodity	Sample number given by the laboratory	Residues of acetamiprid [mg/kg]
20SGS30-01 1	S1 = 14(±1) DBH*	Leaves	DPL/198/2020/1U	<LOD
20SGS30-01 2		Roots	DPL/198/2020/2U	<LOD
20SGS30-01 3		Leaves	DPL/198/2020/3T	<LOD
20SGS30-01 4		Roots	DPL/198/2020/4T	<LOD
20SGS30-01 5	S2 = BBCH 49	Leaves	DPL/198/2020/5U	<LOD
20SGS30-01 6		Roots	DPL/198/2020/6U	<LOD
20SGS30-01 7		Leaves	DPL/198/2020/7T	<LOD
20SGS30-01 8		Roots	DPL/198/2020/8T	<LOD

*<LOD - lower than the Limit of Detection (LOD = 0.003 mg/kg).

*<LOQ – lower than the Limit of Quantification (LOQ = 0.01 mg/kg)

*DBH – Days Before Harvest

Blank and fortification samples:

Quality control samples - leaves

Sample Name	Result [mg/kg]	Recovery [%]
leaves matrix blank.lcd	< LOD	-
leaves PK1 0,01 mg-kg.lcd	0.0089	89.0
leaves PK1 0,10 mg-kg.lcd	0.090	89.8
leaves PK2 0,01 mg-kg.lcd	0.0091	91.1
leaves PK2 0,10 mg-kg.lcd	0.097	97.3

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

Quality control samples - roots

Sample Name	Result [mg/kg]	Recovery [%]
roots matrix blank.lcd	< LOD	-
roots PK1 0,01 mg-kg.lcd	0.0098	97.9
roots PK1 0,10 mg-kg.lcd	0.096	96.1
roots PK2 0,01 mg-kg.lcd	0.0095	95.4
roots PK2 0,10 mg-kg.lcd	0.097	96.9

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

Conclusion:

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).

A 2.1.3.2.2 Study 2

Comments of zRMS:	<p>One semi decline study trial was established in Poland in 2020 (trial site Chwastnica, zip code 55-216). One application was performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) in BBCH 19.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP). The Applicant provided bridging studies. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of detection (LOD) of the analytical method was 0.003 mg/kg; limit of quantification (LOQ) was 0.01 mg/kg.</p> <p>Sugar beet roots and leaves samples from the field trials were analysed for</p>
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	<p>residues of acetamiprid. Residues in all analysed samples were below LOD. Max. storage interval between sampling and analysis: about 3 months. Stability studies cover 12 months for high water matrices. The study is accepted. The study results used in the evaluation: sugar beet, roots: $1 \times < 0.003 \text{ mg/kg}$ sugar beet, leaves: $1 \times < 0.003 \text{ mg/kg}$</p>
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Reference:	KCA 6.3
Report	Magnitude of the residue of acetamiprid in Sugar beet (Raw Agricultural Commodity) after one applications of CHR/I/ACE 200 SE one semi decline curve trial in Poland – 2020. Tomasz Peda, 2021, 20SGS29
Guideline(s):	OECD Guidline Document for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANCO/825/00, rev. 8.1; 16/11/2010 SANCO/3029/99, rev. 4; 11/07/2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Methods:

Field trial was established on sugar beet production, grown in a typical way in the test country. Trial consisted of one untreated plot U and one treated plot T. Plots were of sufficient size to generate the desired specimen quantities. For untreated and treated plots they consisted of minimum 45m^2 for semi decline curve study. Around the treated and untreated plots a buffer zone (zone where no forbidden products are applied) of at least 10m was set up. The untreated plot was separated by a buffer zone of at least 10 m from treated plot.

The application equipment consisted of boom sprayer.

The foliar applications closely simulated commercial-type treatments.

Calibrations of the spray equipment at the trial site were accomplished by using the volume/time method for liquid applications.

Before each application, the spray equipment and the sprayer speed were calibrated to deliver an average volume of spray mixture per unit time at a given pressure resulting in the desired spray volume per hectare.

CHR/I/ADEL 200 SE was mixed with water , no adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 0.2 l/ha of formulated product (FP) per application, equivalent to 40 a.s./ha of acetamiprid. Applications were made at a target water volume of $300\text{-}400 \text{ l/ha}$ of mixture according to good agricultural practice.

Specimen collection:

Trial number: 20SGS29-01

Plot number	Specimen Id		Sampling occasion	Specimen type	Minimum sample size	Storage Condition
U	20SGS29-01	1	S1 = 14(±1)DBH	Leaves	12 units; 1 kg	frozen
U	20SGS29-01	1R			12 units; 1 kg	frozen
U	20SGS29-01	2		Roots	12 units; 1 kg	frozen
U	20SGS29-01	2R			12 units; 1 kg	frozen
T	20SGS29-01	3		Leaves	12 units; 1 kg	frozen
T	20SGS29-01	3R			12 units; 1 kg	frozen
T	20SGS29-01	4		Roots	12 units; 1 kg	frozen
T	20SGS29-01	4R			12 units; 1 kg	frozen
U	20SGS29-01	5	S2 = BBCH 49	Leaves	12 units; 1 kg	frozen
U	20SGS29-01	5R			12 units; 1 kg	frozen
U	20SGS29-01	6		Roots	12 units; 1 kg	frozen
U	20SGS29-01	6R			12 units; 1 kg	frozen
T	20SGS29-01	7		Leaves	12 units; 1 kg	frozen
T	20SGS29-01	7R			12 units; 1 kg	frozen
T	20SGS29-01	8		Roots	12 units; 1 kg	frozen
T	20SGS29-01	8R			12 units; 1 kg	frozen

*DBH – Days Before Harvest

Residues concentration detected in analysed field samples:

Trial 20SGS29-01

Sample name	Timing	Type of commodity	Sample number given by the laboratory	Residues of acetamiprid [mg/kg]
20SGS29-01 1	S1 = 14(±1) DBH*	Leaves	DPL/197/2020/01U	<LOD
20SGS29-01 2		Roots	DPL/197/2020/02U	<LOD
20SGS29-01 3		Leaves	DPL/197/2020/03T	<LOD
20SGS29-01 4		Roots	DPL/197/2020/04T	<LOD
20SGS29-01 5	S2 = BBCH 49	Leaves	DPL/197/2020/05U	<LOD
20SGS29-01 6		Roots	DPL/197/2020/06U	<LOD
20SGS29-01 7		Leaves	DPL/197/2020/07T	<LOD
20SGS29-01 8		Roots	DPL/197/2020/08T	<LOD

*<LOD - lower than the Limit of Detection (LOD = 0,03 mg/kg).

*<LOQ – lower than the Limit of Quantification (LOQ = 0,01 mg/kg)

*DBH – Days Before Harvest

Blank and fortification samples:

Quality control samples - leaves

Sample Name	Result [mg/kg]	Recovery [%]
leaves matrix blank.lcd	< LOD	-
leaves PK1 0,01 mg-kg.lcd	0.0089	89.0
leaves PK1 0,10 mg-kg.lcd	0.090	89.8
leaves PK2 0,01 mg-kg.lcd	0.0091	91.1
leaves PK2 0,10 mg-kg.lcd	0.097	97.3

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

Quality control samples - roots

Sample Name	Result [mg/kg]	Recovery [%]
roots matrix blank.lcd	< LOD	-
roots PK1 0,01 mg-kg.lcd	0.0098	97.9
roots PK1 0,10 mg-kg.lcd	0.096	96.1
roots PK2 0,01 mg-kg.lcd	0.0095	95.4
roots PK2 0,10 mg-kg.lcd	0.097	96.9

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

Conclusion:

This study was fully performed as anticipated, in accordance with the study plan and the amendment issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).

A 2.1.3.2.3 Study 3

Comments of zRMS:	<p>One trial was established in Germany in 2021. One application was performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) in BBCH 19.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP). The Applicant provided bridging studies. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of detection (LOD) of the analytical method was 0.003 mg/kg; limit of quantification (LOQ) was 0.01 mg/kg.</p> <p>Sugar beet roots and leaves samples from the field trials were analysed for residues of acetamiprid. Residues in all analysed samples were below LOD.</p> <p>Max. storage interval between sampling and analysis: about 5 months. Stability studies cover 12 months for high water matrices.</p>
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	The study is accepted. The study results used in the evaluation: sugar beet, roots: $1 \times < 0.003 \text{ mg/kg}$ sugar beet, leaves: $1 \times < 0.003 \text{ mg/kg}$
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Reference: KCA 6.3

Report Magnitude of the residue of Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ACE 200 SE – one single harvest trial in Germany - 2021. Katarzyna Wanczyk, 2022, 21SGS26

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
 Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997
 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
 SANTE/2020/12830 rev.1, 24/02/2021

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and Methods:

One harvest trial (HS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application was performed in trial with boom sprayer on the treated plots at the target dose rate of 0,2 l/ha (CHR/I/ACE 200 SE) .For the test item CHR/I/ACE 200 SE the reported dose rate was 0,196 l/ha.

The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 293,3 l/ha.

Foliar applications were performed in BBCH 19.

The spray mixture volume remaining after application was measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rate was verified by the Study Director.

Deviation to the target rates were between $\pm 5\%$ as requested in the study plan (actually it was -2,2).

In harvest trial (HS), RAC specimens for analyses (Leaves with top and roots) were collected at:

S1 - Commercial Harvest

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of $\leq -18^\circ \text{C}$ on the day of sampling, within 12 hours after sampling.

Specimen collection:

Specimen number	Pl ot ID	Actual sampling date	Growth Stage ⁽¹⁾	Sampling event	Actual DAL A*	Matrix	Minimum sample size	Weight specimen (g)	Starting time of specimen collection	Time in freezer	Conditions during transport	Target storage temperature (°C)	Shipment date ⁽²⁾
21SGS26-01 1	U	13.09.2021	49	S1	95	Leaves with top	12 units, 1,0 kg	9217,2	08:37	10:28	≤ -18	≤ -18	28.10.2021
21SGS26-01 1R								6961,2	08:37	10:28	≤ -18	≤ -18	-
21SGS26-01 2	U					12 units, 1,0 kg	2310,8	08:37	10:29	≤ -18	≤ -18	28.10.2021	
21SGS26-01 2R								2300	08:37	10:29	≤ -18	≤ -18	-
21SGS26-01 3	T	13.09.2021	49		95	Leaves with top	12 units, 1,0 kg	9118,0	09:18	10:31	≤ -18	≤ -18	28.10.2021
21SGS26-01 3R								8005,2	09:18	10:31	≤ -18	≤ -18	-
21SGS26-01 4	T					12 units, 1,0 kg	2221,4	09:18	10:32	≤ -18	≤ -18	28.10.2021	
21SGS26-01 4R								2106,0	09:18	10:32	≤ -18	≤ -18	-

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues [mg/kg] acetamiprid
21SGS26-01 1	S1 =BBCH 49/CH*	Leaves with top	DPL/26/2021/01U	<LOD
21SGS26-01 2		Roots	DPL/26/2021/02U	<LOD
21SGS26-01 3		Leaves with top	DPL/26/2021/03T	<LOD
21SGS26-01 4		Roots	DPL/26/2021/04T	<LOD

*CH-Commercial Harvest

Blank and fortification samples:

Table 11. Quality control samples - roots

Sample Name	Result [mg/kg]	Recovery [%]
roots matrix blank.lcd	< LOD	-
roots PK1 0,01 mg-kg.lcd	0.0095	94.6
roots PK1 0,10 mg-kg.lcd	0.096	96.1
roots PK2 0,01 mg-kg.lcd	0.0095	94.7
roots PK2 0,10 mg-kg.lcd	0.10	99.6
roots cal 100 ppb'.lcd	0.11	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Table 12. Quality control samples - leaves

Sample Name	Result [mg/kg]	Recovery [%]
leaves matrix blank.lcd	< LOD	-
leaves PK1 0,01 mg-kg.lcd	0.011	105.8
leaves PK1 0,10 mg-kg.lcd	0.10	103.5
leaves PK2 0,01 mg-kg.lcd	0.0099	99.2
leaves PK2 0,10 mg-kg.lcd	0.098	97.9
leaves cal 100 ppb'.lcd	0.098	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

The method was validated according to SANCO/3029/99, rev. 4 guidelines. The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for sugar beet, respectively. There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of acetamiprid meets the criteria of SANTE/2020/12830,Rev.1 in terms of precision, accuracy and uncertainty.

A 2.1.3.2.4 Study 4

Comments of zRMS:	<p>One trial was established in Northern France in 2021. One application was performed on the treated plots at the target dose rate of 0.2 l/ha CHR/I/ACE 200 SE (equivalent to 40 g acetamiprid /ha) in BBCH 19.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP). The Applicant provided bridging studies. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of detection (LOD) of the analytical method was 0.003 mg/kg; limit of quantification (LOQ) was 0.01 mg/kg.</p> <p>Sugar beet roots and leaves samples from the field trials were analysed for residues of acetamiprid. Residues in roots samples were below LOD, residues in leaves samples were below LOQ..</p>
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	Max. storage interval between sampling and analysis: about 5 months. Stability studies cover 12 months for high water matrices. The study is accepted. The study results used in the evaluation: sugar beet, roots: $1 \times < 0.003 \text{ mg/kg}$ sugar beet, leaves: $1 \times < 0.01 \text{ mg/kg}$
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Reference:	KCA 6.3
Report	Magnitude of the residue of Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ACE 200 SE – one single harvest trial in Northern France – 2021, Katarzyna Wanczyk, 2022, 21SGS27
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830 rev.1, 24/02/2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and Methods:

One harvest trial (HS) was established in Northern France. Trial consisted of one untreated plot U and one treated plot T.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.
One typical for insecticide application was performed in trial with boom sprayer on the treated plots at the target dose rate of 0,2 l/ha (CHR/I/ACE 200 SE) .For the test item CHR/I/ACE 200 SE the reported dose rate was 0,196 l/ha.

The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 343,3 l/ha.

Foliar applications were performed in BBCH 19.

The spray mixture volume remaining after application was measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rate was verified by the Study Director.

Deviation to the target rates were between $\pm 5\%$ as requested in the study plan (actually it was - 2,0).

In harvest trial (HS), RAC specimens for analyses (Leaves with top and roots) were collected at:

S1 - Commercial Harvest

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.

RAC specimens were put in deep freezing conditions at a target temperature of $\leq -18^\circ \text{C}$ on the day of sampling, within 12 hours after sampling

Specimen collection:

Specimen collection.													
Specimen number	Plot ID	Actual sampling date	Growth Stage ⁽¹⁾	Sampling event	Actual DAL A*	Matrix	Minimum sample size	Weight specimen (g)	Starting time of specimen collection	Time in freezer	Conditions during transport	Target storage temperature (°C)	Shipment date ⁽²⁾
21SGS27-01 1	U	02.09.2021	49	S1	84	Leaves with top	12 units, 1,0 kg	3998	08:17	09:30	Frozen	≤ -18	26.10.2021
21SGS27-01 1R								4152	08:17	09:30	Frozen	≤ -18	-
21SGS27-01 2	U					12 units, 1,0 kg	2978	08:17	09:30	Frozen	≤ -18	26.10.2021	
21SGS27-01 2R								3120	08:17	09:30	Frozen	≤ -18	-
21SGS27-01 3	T	13.09.2021	49		84	Leaves with top	12 units, 1,0 kg	3680	08:37	09:30	Frozen	≤ -18	26.10.2021
21SGS27-01 3R								4000	08:37	09:30	Frozen	≤ -18	-
21SGS27-01 4	T					12 units, 1,0 kg	3142	08:37	09:30	Frozen	≤ -18	26.10.2021	
21SGS27-01 4R								3342	08:37	09:30	Frozen	≤ -18	-

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues [mg/kg] acetamidiprid
21SGS27-01 1	S1 =BBCH 49 CH*	Leaves _{wi}	DPL/27/2021/01U	<LOD
21SGS27-01 2		Roots	DPL/27/2021/02U	<LOD
21SGS27-01 3		Leaves _{wi}	DPL/27/2021/03T	<LOQ
21SGS27-01 4		Roots	DPL/27/2021/04T	<LOD

Blank and fortification samples:

Table 11. Quality control samples - roots

Sample Name	Result [mg/kg]	Recovery [%]
roots matrix blank.lcd	< LOD	-
roots PK1 0,01 mg-kg.lcd	0.0095	94.6
roots PK1 0,10 mg-kg.lcd	0.096	96.1
roots PK2 0,01 mg-kg.lcd	0.0095	94.7
roots PK2 0,10 mg-kg.lcd	0.10	99.6
roots cal 100 ppb'.lcd	0.11	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Table 12. Quality control samples - leaves

Sample Name	Result [mg/kg]	Recovery [%]
leaves matrix blank.lcd	< LOD	-
leaves PK1 0,01 mg-kg.lcd	0.011	105.8
leaves PK1 0,10 mg-kg.lcd	0.10	103.5
leaves PK2 0,01 mg-kg.lcd	0.0099	99.2
leaves PK2 0,10 mg-kg.lcd	0.098	97.9
leaves cal 100 ppb'.lcd	0.098	-

LOD = 0.003 mg/kg, LOQ = 0.010 mg/kg

Conclusion:

The method was validated according to SANCO/3029/99, rev. 4 guidelines. The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for sugar beet, respectively. There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of acetamiprid meets the criteria of SANTE/2020/12830, Rev.1 in terms of precision, accuracy and uncertainty.

Sugar beet summary for SC formulation:

Report-No. Location	Commodity	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i./ha	Water l/ha	Kg a.i./hl						
23SGS40, Poland, Kolonia Bodzanowska	Sugar beet/ Zagłoba	1) 13.04.2023 2) 29.09.2023	0.040	293.3	0.0136	14.06.2023	BBCH 19	Whole plants	0.74	0	LOQ=0.005 mg/kg
								Whole plants	0.27	5	
								Whole plants	0.074	13	
								Whole plants	0.029	22	
								Leaves	<0.001	107	
								Roots	<0.001		
23SGS42, Northern France, Aumenancourt	Sugar beet/ Lunella KWS	1) 04.04.2023 2) 15.10.2023	0.042	261.7	0.0160	31.07.2023	BBCH 19	Leaves	<0.001	57	LOQ=0.005 mg/kg
								Roots	<0.001		
23SGS43, Germany, Schleswig- Holstein	Sugar beet/ Strauß	1) 13.05.2023 2) 10.10.2023	0.0390	243.3	0.0160	07.07.2023	BBCH 19	Leaves	<0.001	95	LOQ=0.005 mg/kg
								Roots	<0.001		

23SGS44, Hungary, Hajdu-Bihar	Sugar beet/ Gazeta	1) 20.04.2023 2) 28.09.2023	0.0390	293.3	0.0132	07.06.2023	BBCH 19	Whole plants	1.12	0	LOQ=0.005 mg/kg
								Whole plants	0.14	5	
								Whole plants	0.088	15	
								Whole plants	0.0097	22	
								Leaves	<0.001	107	
								Roots	<0.001		

A 2.1.3.2.5 Study 5

Comments of zRMS:	<p>One trial was established in Poland in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid/ha and 4.8 g of deltamethrin) in BBCH 19.</p> <p>Acetamiprid</p> <p>Root, leaves and whole plant samples of treated and untreated sugar beets from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for sugar beets was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection.</p> <p>The limit of detection (LOD) of the analytical method was 0.001 mg/kg; limit of quantification (LOQ) was 0.005 mg/kg.</p> <p>Residues in roots and leaves samples were below LOD.</p> <p>Max. storage interval between sampling and analysis: about 4 months. Stability studies cover 12 months for high water matrices.</p> <p>The study is accepted.</p> <p>The study results used in the evaluation:</p> <p>sugar beet, roots: 1 x < 0.001 mg/kg</p> <p>sugar beet, leaves: 1 x < 0.001 mg/kg</p>
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Reference:

KCA 6.3

Report

Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one decline curve study trial in Poland - 2023, Peda, T., Głowiak, K., 2024, 23SGS40

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023

Deviations:

No

GLP:

Yes

Acceptability:

Yes

Materials and Methods:

The objective of the study was to determine the residue level of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet after one application of formulated product CHR/I/ADEL 280 SC under cultural practice typical for sugar beet production. Decline Curve Study trial (DCS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g of acetamiprid and 4,8 g of deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,158 l/ha (295,8 l/ha water).

Application was performed at BBCH 19.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -1,3%.

RAC specimens for analyses were collected:

- S1 (Whole plant) – 0 DALA
- S2 (Whole plant) – 5 DALA
- S3 (Whole plant) – 14(±1) DALA
- S4 (Whole plant) – BBCH 37
- S5 (Leaves with tops; Root) – BBCH 49 / CH

Residues concentration detected in analysed field samples:

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]		
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*
1	0 DALA	23SGS40-01 1	sugar beet (whole plant)	DPL/72/2023/01U	<LOD	<LOD	<LOD
2		23SGS40-01 2	sugar beet (whole plant)	DPL/72/2023/02T	0.74	<LOQ	0.74
3	5 DALA	23SGS40-01 3	sugar beet (whole plant)	DPL/72/2023/03T	0.27	0.012	0.28
4	14(±1) DALA	23SGS40-01 4	sugar beet (whole plant)	DPL/72/2023/04T	0.074	0.0088	0.083
5	BBCH 37	23SGS40-01 5	sugar beet (whole plant)	DPL/72/2023/05T	0.029	0.0058	0.035
6	BBCH 49 / CH	23SGS40-01 6	sugar beet (root)	DPL/72/2023/06U	<LOD	<LOD	<LOD
7		23SGS40-01 7	sugar beet (leaves with tops)	DPL/72/2023/07U	<LOD	<LOD	<LOD
8		23SGS40-01 8	sugar beet (root)	DPL/72/2023/08T	<LOD	<LOD	<LOD
9		23SGS40-01 9	sugar beet (leaves with tops)	DPL/72/2023/09T	<LOD	<LOD	<LOD

*sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

DALA – Days After Last Application, BBCH – According to BBCH scale

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values,

LOD = 0.001 mg/kg for acetamiprid, LOD = 0.001 mg/kg for acetamiprid-N-desmethyl

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl

LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

Blank and fortification samples:

Table 9. Quality control samples – Acetamiprid (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0047	94.8
whole plant, PK1 0,05 mg-kg.lcd	0.056	112.9
whole plant, PK2 0,005 mg-kg.lcd	0.0050	100.1
whole plant, PK2 0,05 mg-kg.lcd	0.050	99.1

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 10. Quality control samples – Acetamiprid-N-desmethyl (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0048	95.5
whole plant, PK1 0,05 mg-kg.lcd	0.056	111.5
whole plant, PK2 0,005 mg-kg.lcd	0.0042	83.4
whole plant, PK2 0,05 mg-kg.lcd	0.053	105.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 11. Quality control samples – Acetamiprid (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0052	104.1
whole plant, PK1 0,05 mg-kg.lcd	0.054	107.3
whole plant, PK2 0,005 mg-kg.lcd	0.0053	105.1
whole plant, PK2 0,05 mg-kg.lcd	0.053	105.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of treated samples 12.07.2023:

Table 12. Quality control samples – Acetamiprid (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0050	99.2
whole plant, PK1 0,05 mg-kg.lcd	0.050	99.7
whole plant, PK2 0,005 mg-kg.lcd	0.0049	97.2
whole plant, PK2 0,05 mg-kg.lcd	0.048	95.3

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 13. Quality control samples – (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0045	89.7
whole plant, PK1 0,05 mg-kg.lcd	0.050	99.2
whole plant, PK2 0,005 mg-kg.lcd	0.0044	88.2
whole plant, PK2 0,05 mg-kg.lcd	0.046	91.5

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of treated samples 26.10.2023:

Table 14. Quality control samples – Acetamiprid (roots)

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0049	97.8
roots, PK1 0,05 mg-kg.lcd	0.051	102.5
roots, PK2 0,005 mg-kg.lcd	0.0052	103.3
roots, PK2 0,05 mg-kg.lcd	0.051	102.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 15. Quality control samples – Acetamiprid-N-desmethyl (roots)

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0051	102.5
roots, PK1 0,05 mg-kg.lcd	0.051	101.1
roots, PK2 0,005 mg-kg.lcd	0.0051	102.2
roots, PK2 0,05 mg-kg.lcd	0.051	103.0

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 16. Quality control samples – Acetamiprid (leaves)

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kg.lcd	0.050	100.9
leaves, PK1 0,05 mg-kg.lcd	0.050	99.6
leaves, PK2 0,005 mg-kg.lcd	0.0049	97.4
leaves, PK2 0,05 mg-kg.lcd	0.052	103.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 17. Quality control samples – Acetamiprid-N-desmethyl (leaves)

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kg.lcd	0.0047	94.5
leaves, PK1 0,05 mg-kg.lcd	0.051	102.4
leaves, PK2 0,005 mg-kg.lcd	0.0049	97.9
leaves, PK2 0,05 mg-kg.lcd	0.052	103.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023

The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl for sugar beet (whole plant, leaves and roots) and for ‘sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid’ limit of quantification was 0.01 mg/kg.

The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 – 120%).

A 2.1.3.2.6 Study 6

Comments of zRMS:	<p>One trial was established in Northern France in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid/ha and 4.8 g of deltamethrin) in BBCH 19.</p> <p>Acetamiprid</p> <p>Root, leaves and whole plant samples of treated and untreated sugar beets from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for sugar beets was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection.</p> <p>The limit of detection (LOD) of the analytical method was 0.001 mg/kg; limit of quantification (LOQ) was 0.005 mg/kg.</p> <p>Residues in roots and leaves samples were below LOD.</p> <p>Max. storage interval between sampling and analysis: about 1 month. Stability studies cover 12 months for high water matrices.</p> <p>The study is accepted.</p> <p>The study results used in the evaluation:</p> <p>sugar beet, roots: $1 \times < 0.001 \text{ mg/kg}$</p> <p>sugar beet, leaves: $1 \times < 0.001 \text{ mg/kg}$</p>
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Reference:

KCA 6.3

Report

Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one harvest study trial in Northern France – 2023, Peda, T., Głowiak, K., 2024, 23SGS42

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023

Deviations:

No

GLP:

Yes

Acceptability:

Yes

Materials and Methods:

The objective of the study was to determine the residue level of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet after one application of formulated product CHR/I/ADEL 280 SC under cultural practice typical for sugar beet production.

Harvest Study trial (HS) was established in Northern France. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g of acetamiprid and 4,8 g of deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,167 l/ha (261,7 l/ha water).

Application was performed at BBCH 19.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was +4,4%.

RAC specimens for analyses were collected:

- S1 (Leaves with tops; Root) – BBCH 49 / CH

Residues concentration detected in analysed field samples:

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]		
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*
1	BBCH 49 / CH	23SGS42-01 1	sugar beet (root)	DPL/74/2023/01U	<LOD	<LOD	<LOD
2		23SGS42-01 2	sugar beet (leaves with tops)	DPL/74/2023/02U	<LOD	<LOD	<LOD
3		23SGS42-01 3	sugar beet (root)	DPL/74/2023/03T	<LOD	<LOD	<LOD
4		23SGS42-01 4	sugar beet (leaves with tops)	DPL/74/2023/04T	<LOD	<LOD	<LOD

*sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

BBCH – According to BBCH scale; CH – Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values,

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for acetamiprid-N-desmethyl

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl

LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

Blank and fortification samples:

Table 9. Quality control samples – Acetamiprid (roots)

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0049	97.8
roots, PK1 0,05 mg-kg.lcd	0.051	102.5
roots, PK2 0,005 mg-kg.lcd	0.0052	103.3
roots, PK2 0,05 mg-kg.lcd	0.051	102.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 10. Quality control samples – Acetamiprid-N-desmethyl (roots)

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0051	102.5
roots, PK1 0,05 mg-kg.lcd	0.051	101.1
roots, PK2 0,005 mg-kg.lcd	0.0051	102.2
roots, PK2 0,05 mg-kg.lcd	0.051	103.0

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 11. Quality control samples – Acetamiprid (leaves)

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kg.lcd	0.050	100.9
leaves, PK1 0,05 mg-kg.lcd	0.050	99.6
leaves, PK2 0,005 mg-kg.lcd	0.0049	97.4
leaves, PK2 0,05 mg-kg.lcd	0.052	103.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 12. Quality control samples – Acetamiprid-N-desmethyl (leaves)

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kg.lcd	0.0047	94.5
leaves, PK1 0,05 mg-kg.lcd	0.051	102.4
leaves, PK2 0,005 mg-kg.lcd	0.0049	97.9
leaves, PK2 0,05 mg-kg.lcd	0.052	103.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023
 The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl for sugar beet (leaves and roots) and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.01 mg/kg.
 The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 – 120%).

A 2.1.3.2.7 Study 7

Comments of zRMS:	<p>One trial was established in Germany in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid/ha and 4.8 g of deltamethrin) in BBCH 19.</p> <p>Acetamiprid</p> <p>Root, leaves and whole plant samples of treated and untreated sugar beets from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for sugar beets was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection.</p> <p>The limit of detection (LOD) of the analytical method was 0.001 mg/kg; limit of quantification (LOQ) was 0.005 mg/kg.</p> <p>Residues in roots and leaves samples were below LOD.</p> <p>Max. storage interval between sampling and analysis: about 1 month. Stability studies cover 12 months for high water matrices.</p> <p>The study is accepted.</p> <p>The study results used in the evaluation:</p> <p>sugar beet, roots: $1 \times < 0.001$ mg/kg</p> <p>sugar beet, leaves: $1 \times < 0.001$ mg/kg</p>
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Reference:	KCA 6.3
Report	Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one harvest study trial in Germany – 2023, Peda, T., Niewelt-Stasiak, S., 2024, 23SGS43
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes

Acceptability: Yes

Materials and Methods:

The objective of the study was to determine the residue level of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet after one application of formulated product CHR/I/ADEL 280 SC under cultural practice typical for sugar beet production.

Harvest Study trial (HS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g of acetamiprid and 4,8 g of deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,156 l/ha (243,3 l/ha water).

Application was performed at BBCH 19.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -2,7%.

RAC specimens for analyses were collected:

- S1 (Leaves with tops; Root) – BBCH 49 / CH

Residues concentration detected in analysed field samples:

The following residues concentration was determined in the field samples analyzed on 09.11.2023:

Table 8. Residue concentrations of acetamiprid and acetamiprid-N-desmethyl detected in analyzed field samples (Study No.:23SGS43, Trial No.: 23SGS43-01)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]		
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*
1	BBCH 49 / CH	23SGS43-01 1	sugar beet (root)	DPL/75/2023/01U	<LOD	<LOD	<LOD
2		23SGS43-01 2	sugar beet (leaves with tops)	DPL/75/2023/02U	<LOD	<LOD	<LOD
3		23SGS43-01 3	sugar beet (root)	DPL/75/2023/03T	<LOD	<LOD	<LOD
4		23SGS43-01 4	sugar beet (leaves with tops)	DPL/75/2023/04T	<LOD	<LOD	<LOD

*sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

BBCH – According to BBCH scale; CH – Commercial Harvest

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values.

LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for acetamiprid-N-desmethyl

LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl

LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

Blank and fortification samples:

Table 9. Quality control samples – acetamiprid in roots

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0049	97.1
roots, PK1 0,05 mg-kg.lcd	0.054	108.1
roots, PK2 0,005 mg-kg.lcd	0.0051	102.0
roots, PK2 0,05 mg-kg.lcd	0.055	110.9

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 10. Quality control samples – acetamiprid-N-desmethyl in roots

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0051	102.8
roots, PK1 0,05 mg-kg.lcd	0.051	102.7
roots, PK2 0,005 mg-kg.lcd	0.0047	94.8
roots, PK2 0,05 mg-kg.lcd	0.055	109.7

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 11. Quality control samples – acetamiprid in leaves

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kg.lcd	0.0045	90.4
leaves, PK1 0,05 mg-kg.lcd	0.050	99.8
leaves, PK2 0,005 mg-kg.lcd	0.0051	102.2
leaves, PK2 0,05 mg-kg.lcd	0.048	96.3

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 12. Quality control samples – scetamiprid-N-desmethyl in leaves

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kg.lcd	0.0047	93.0
leaves, PK1 0,05 mg-kg.lcd	0.051	101.9
leaves, PK2 0,005 mg-kg.lcd	0.0050	100.5
leaves, PK2 0,05 mg-kg.lcd	0.051	102.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023
 The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl for sugar beet (leaves and roots) and for “sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid” limit of quantification was 0.01 mg/kg. The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 – 120%).

A 2.1.3.2.8 Study 8

Comments of zRMS:	<p>One trial was established in Hungary in 2023. One application was performed on the treated plots at the target dose rate of 0.16 l/ha CHR/I/ADEL 280 SC (equivalent to 40 g acetamiprid/ha and 4.8 g of deltamethrin) in BBCH 19.</p> <p>Acetamiprid</p> <p>Root, leaves and whole plant samples of treated and untreated sugar beets from the field trials were analysed for residues of acetamiprid and acetamiprid-N-desmethyl. Taken into account that the residue definition for monitoring and risk assessment for sugar beets was establish as acetamiprid only, the acetamiprid results were used for further evaluation.</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection.</p> <p>The limit of detection (LOD) of the analytical method was 0.001 mg/kg; limit of quantification (LOQ) was 0.005 mg/kg.</p> <p>Residues in roots and leaves samples were below LOD.</p> <p>Max. storage interval between sampling and analysis: about 4 months. Stability studies cover 12 months for high water matrices.</p> <p>The study is accepted.</p> <p>The study results used in the evaluation:</p> <p>sugar beet, roots: 1 x < 0.001 mg/kg</p> <p>sugar beet, leaves: 1 x < 0.001 mg/kg</p>
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Reference:

KCA 6.3

Report

Magnitude of residue for sum of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet (Raw Agricultural Commodity) after one application of CHR/I/ADEL 280 SC – one decline curve study trial in Hungary - 2023, Peda, T., Niewelt-Stasiak, S., 2024, 23SGS44

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023

Deviations:

No

GLP:

Yes

Acceptability: Yes

Materials and Methods:

The objective of the study was to determine the residue level of Acetamiprid and N-desmethyl-acetamiprid (IM-2-1) expressed as Acetamiprid in sugar beet after one application of formulated product CHR/I/ADEL 280 SC under cultural practice typical for sugar beet production. Decline Curve Study trial (DCS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T.

Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.

One typical for insecticide application of CHR/I/ADEL 280 SC was performed with boom sprayer on the treated plot at the target dose rate of 0,16 l/ha, equivalent to 40 g of acetamiprid and 4,8 g of deltamethrin. Spray volume was 200-300 l/ha according to Good Agricultural Practice. The reported dose rate of test item was 0,157 l/ha (293,3 l/ha water).

Application was performed at BBCH 19.

Remaining spray mixture after application was measured and the volume applied to the treated plot was calculated to verify delivery rate. Deviation to the target rate was -2,2%.

RAC specimens for analyses were collected:

- S1 (Whole plant) – 0 DALA
- S2 (Whole plant) – 5 DALA
- S3 (Whole plant) - 14(±1) DALA
- S4 (Whole plant) – BBCH 37
- S5 (Leaves with tops; Root) – BBCH 49 / CH

Residues concentration detected in analysed field samples:

The following residues concentration was determined in the field samples analyzed on 04.07.2023, 05.07.2023, 12.07.2023 and 13.10.2023:

Table 8. Residue concentrations of acetamiprid and acetamiprid-N-desmethyl detected in analyzed field samples (Study No.:23SGS44, Trial No.: 23SGS44-01)

No	Timing	Study sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]		
					Acetamiprid	Acetamiprid-N-desmethyl	Sum of acetamiprid and acetamiprid-N-desmethyl*
1	0 DALA	23SGS44-01 1	sugar beet (whole plant)	DPL/76/2023/01U	<LOD	<LOD	<LOD
2		23SGS44-01 2	sugar beet (whole plant)	DPL/76/2023/02T	1.12	<LOQ	1.12
3	5 DALA	23SGS44-01 3	sugar beet (whole plant)	DPL/76/2023/03T	0.14	<LOQ	0.14
4	14(±1) DALA	23SGS44-01 4	sugar beet (whole plant)	DPL/76/2023/04T	0.088	0.0074	0.096
5	BBCH 37	23SGS44-01 5	sugar beet (whole plant)	DPL/76/2023/05T	0.0097	<LOQ	<LOQ
6	BBCH 49 / CH	23SGS44-01 6	sugar beet (root)	DPL/76/2023/06U	<LOD	<LOD	<LOD
7		23SGS44-01 7	sugar beet (leaves with tops)	DPL/76/2023/07U	<LOD	<LOD	<LOD
8		23SGS44-01 8	sugar beet (root)	DPL/76/2023/08T	<LOD	<LOD	<LOD
9		23SGS44-01 9	sugar beet (leaves with tops)	DPL/76/2023/09T	<LOD	<LOD	<LOD

*sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid
DALA – Days After Last Application, BBCH – According to BBCH scale

Residues are not corrected for procedural recoveries;
 Calculation based on unrounded values,
 LOD = 0.001 mg/kg for acetamiprid; LOD = 0.001 mg/kg for acetamiprid-N-desmethyl
 LOQ = 0.005 mg/kg for acetamiprid; LOQ= 0.005 mg/kg for acetamiprid-N-desmethyl
 LOQ = 0.01 mg/kg for sum of acetamiprid and acetamiprid-N-desmethyl

Blank and fortification samples:

Table 9. Quality control samples – Acetamiprid (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0047	94.8
whole plant, PK1 0,05 mg-kg.lcd	0.056	112.9
whole plant, PK2 0,005 mg-kg.lcd	0.0050	100.1
whole plant, PK2 0,05 mg-kg.lcd	0.050	99.1

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 10. Quality control samples – Acetamiprid-N-desmethyl (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0048	95.5
whole plant, PK1 0,05 mg-kg.lcd	0.056	111.5
whole plant, PK2 0,005 mg-kg.lcd	0.0042	83.4
whole plant, PK2 0,05 mg-kg.lcd	0.053	105.2

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of diluted sample 05.07.2023:

Table 11. Quality control samples – Acetamiprid (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0052	104.1
whole plant, PK1 0,05 mg-kg.lcd	0.054	107.3
whole plant, PK2 0,005 mg-kg.lcd	0.0053	105.1
whole plant, PK2 0,05 mg-kg.lcd	0.053	105.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of treated samples 12.07.2023:

Table 12. Quality control samples – Acetamiprid (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0050	99.2
whole plant, PK1 0,05 mg-kg.lcd	0.050	99.7
whole plant, PK2 0,005 mg-kg.lcd	0.0049	97.2
whole plant, PK2 0,05 mg-kg.lcd	0.048	95.3

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 13. Quality control samples – Acetamiprid-N-desmethyl (whole plant)

Sample Name	Result [mg/kg]	Recovery [%]
sample blank.lcd	< LOD	-
whole plant, PK1 0,005 mg-kg.lcd	0.0045	89.7
whole plant, PK1 0,05 mg-kg.lcd	0.050	99.2
whole plant, PK2 0,005 mg-kg.lcd	0.0044	88.2
whole plant, PK2 0,05 mg-kg.lcd	0.046	91.5

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

The following results for matrix blank and fortified samples were obtained during analysis of treated samples 13.10.2023:

Table 14. Quality control samples – Acetamiprid (roots)

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kg.lcd	0.0055	110.2
roots, PK1 0,05 mg-kg.lcd	0.054	107.0
roots, PK2 0,005 mg-kg.lcd	0.0050	100.7
roots, PK2 0,05 mg-kg.lcd	0.052	103.8

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 15. Quality control samples – Acetamiprid-N-desmethyl (roots)

Sample Name	Result [mg/kg]	Recovery [%]
roots, sample blank.lcd	< LOD	-
roots, PK1 0,005 mg-kq.lcd	0.0052	103.3
roots, PK1 0,05 mg-kq.lcd	0.054	108.5
roots, PK2 0,005 mg-kq.lcd	0.0049	97.8
roots, PK2 0,05 mg-kq.lcd	0.053	105.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 16. Quality control samples – Acetamiprid (leaves)

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kq.lcd	0.0054	107.2
leaves, PK1 0,05 mg-kq.lcd	0.049	98.2
leaves, PK2 0,005 mg-kq.lcd	0.0048	96.4
leaves, PK2 0,05 mg-kq.lcd	0.052	103.7

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Table 17. Quality control samples – Acetamiprid-N-desmethyl (leaves)

Sample Name	Result [mg/kg]	Recovery [%]
leaves, sample blank.lcd	< LOD	-
leaves, PK1 0,005 mg-kq.lcd	0.0040	80.3
leaves, PK1 0,05 mg-kq.lcd	0.042	83.5
leaves, PK2 0,005 mg-kq.lcd	0.0040	80.4
leaves, PK2 0,05 mg-kq.lcd	0.044	88.6

LOD = 0.001 mg/kg, LOQ = 0.005 mg/kg

Conclusion:

The method was validated according to SANTE/2020/12830 Rev.2, 14 February 2023

The limit of quantification of the method was established at 0.005 mg/kg for acetamiprid and 0.005 mg/kg for acetamiprid-N-desmethyl for sugar beet (whole plant, leaves and roots) and for "sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid" limit of quantification was 0.01 mg/kg.

The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.2 criteria (accuracy in the range 70 – 120%).

A 2.1.3.3 Oilseed rape (acetamiprid)

Oilseed rape summary:

Report- No. Location	Commodity	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i/ha	Water l/ha	Kg a.i./hl						
B8177/ 95- 061 Dmosin, Nadolna- Kolonia, Lodzkie, Poland/ 2018	Oilseed rape/ FREDDY	1. 25.08.2017 2. - 3. 10.07.2018	51.7	310	16.67	01.06.2018	BBCH 72-73	5g	0.093 acetamiprid for seeds 0.9 acetamiprid for pods	39	Foliar application Date of reception: 35.07.2018 Date of extraction and analysis: 17.09.2018 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B8183/ 57810 Donnelay, Grand-Est, France/ 2018	Oilseed rape/Dariot	1. 20.08.2017 2. - 3. 11.07.2018	48.3	290	16.66	31.05.2018	BBCH 69-71	5g	0.087 acetamiprid for seed 0.115 acetamiprid for pods	41	Foliar application Date of reception: 25.07.2018 Date of extraction and analysis: 17.09.2018 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B8185/ 49430 Durtal, Pays de la Loire, France/ 2018	Oilseed rape/ Extenso	1. 21.08.2017 2. - 3. 26.06.2018	52.8	317	16.67	30.05.2018	BBCH 78	5g	0.089 acetamiprid for seeds 1.13 acetamiprid for pods	27	Foliar application Date of reception: 25.07.2018 Date of extraction: 13.09.2018 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B7241/ 56125 Rudoltice,	Oilseed rape/ Atora	1. 25.08.2016 2. - 3. 02.08.2017	47.2	283	16.67	26.06.2017	BBCH 79	5g	<LOQ acetamiprid for seed	37	Foliar application Date of reception: 17.08.2017 Date of extraction: 13.11.2018

Pardubice, Czech Republic/ 2017									<LOQ acetamiprid for pods		Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B7241/ 59253 La Gorgue, Hauts-de- France, France/ 2017	Oilseed rape/ EXCEPTION	1. 20.09.2016 2. – 3. 14.07.2017	52.2	313	16.67	08.06.2017	BBCH 74	5 g	0.045 acetamiprid for seed 0.086 acetamiprid for pods	36	Foliar application Date of reception: 17.08.2017 Date of extraction and analysis: 25.08.2017 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B7241/ 95001 Biała, Lodzkie, Poland/ 2017	Oilseed rape/ NK TECHNIC	1. 25.08.2016 2. – 3. 20.07.2017	48.7	292	16.67	08.06.2017	BBCH 76-77	5 g	0.014 acetamiprid for seed 0.1 acetamiprid for pods	42	Foliar application Date of reception: 17.08.2017 Date of extraction and analysis: 25.08.2017 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B7241/ 2921 Komarom, Komarom- Esztergom, Hungary/ 2017	Oilseed rape/ GK REKA	1. 09.2016 2. – 3. 21.07.2017	47.3	284	16.66	12.06.2017	BBCH 79	5 g	<LOQ acetamiprid for seed <LOQ acetamiprid for pods	39	Foliar application Date of reception: 17.08.2017 Date of extraction and analysis: 25.08.2017 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.012 mg/kg
B9219/ 51756 Slatina nad Zdobnici, Hradec Kralove, Czech Republic/2019	Oilseedrape/ Architect	1.28.08.2018 2. – 3.01.08.2019	50.5	303	16.67	14.06.2019	BBCH 72	5g	<LOQ for seed 0.015 for seed 0.06 for pods	45	Foliar application Date of reception: 05.09.2019 Date of extraction and analysis: 20.12.2019 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg

zRMS comments:

Comparison of intended and critical EU GAPs:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (kg a.s./ha)	PHI (days)
Rapeseed (code 0401060)				
cGAP EU EFSA Journal 2016;14(2):4385	1st appl.: BBCH 59 2nd appl.: BBCH 80	2 (n.r.)	0.042	n.r.
Intended GAP (major use No 1)	BBCH 10-21	1	0.04	n/a
Intended GAP (major use No 2)	BBCH 30-70	1	0.04	n/a

A 2.1.3.3.1 Study 1

Comments of zRMS:	<p>Analytical part of the B8185 (A 2.1.3.3.6) field study.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP).</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of quantification (LOQ) was 0.012 mg/kg.</p> <p>The presence of residues in OSR seed samples was found to be 0.089 mg/kg</p> <p>Max. storage interval between sampling and analysis: about 4 months. Stability studies cover 12 months for high oil matrices.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Determination of residue of acetamiprid in Oilseed rape (OSR) following foliar applications of APIS 200 SE under field condition Northern France 2018, Grzegorz Paszek, 2018, DPL/70/2018
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC</p> <p>Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for annex II (part A, Section 4) and annex III (Part A section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/2000</p> <p>Guidance document on pesticide residue analytical methods SANCO/825/00, rev. 8.1; 16/11/2010</p> <p>Regulation (EU) 2017/626 of 31 March 2017 amending annexes II and III to regulation (EC) No 396/2005 of the European Parliament and of the council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole,</p>

triazophos, and trifloxystrobin in or on certain products (Text with EEA relevance.)

Deviations: No
GLP: Yes
Acceptability: Yes

Method:

LC-MS/MS Settings:

Instrument settings:

Liquid Chromatograph LCMS-8050 Shimadzu consists of:

Degazer DGU-20AXR

Two pumps LC-20ADXR (Nexera)

Autosampler SIL-20ACXR

Column oven CTO-20AC

Compressor, generator Peak Genius 1051

HPLC column – SynergiTM 4µm Fusian-RP 80 Å, 100 x 2 mm (Phenomenex)

Pumps:

Mode – Binary gradient

Total Flow – 0,25 ml/min

Mobile phase A – 5 mmol ammonium acetate solution in deionized water

Mobile Phase B – 5 mmol ammonium acetate solution in acetonitrile

A conc – 80%

B Conc – 20%

Cooler temp -4°C

Oven temp. 40 °C

Interface: ESI

Interface heater: on

Interface temp: 300 °C

DL temperature: 250 °C

Nebulizing Gas Flow: 3,00 L/min

Heating gas: on

Heating gas flow: 10,0 l/min

Heat block 400 °C

Drying gas: on

Drying gas flow: 10,0 L/min

Residue concentrations detected in analysed field samples:

No	Country	Sponsor's sample identification	Commodity	Sample number given by the laboratory	Result [mg/kg]
1	Northern France	B8185 BM1 / U0 / A	OSR (pods)	DPL/70/2018/01U	< LOQ
2	Northern France	B8185 BM1 / T0 / A	OSR (pods)	DPL/70/2018/02T	3,39
3	Northern France	B8185 BM1 / U14 / A	OSR (pods)	DPL/70/2018/03U	< LOQ
4	Northern France	B8185 BM1 / T14 / A	OSR (pods)	DPL/70/2018/04T	1,13
5	Northern France	B8185 BM1 / U28 / A	OSR (seed)	DPL/70/2018/05U	< LOQ
6	Northern France	B8185 BM1 / T28 / A	OSR (seed)	DPL/70/2018/06T	0,089

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values, LOQ = 0,012 mg/kg

Blank and fortification samples:

Quality control samples (pods)

Sample Name	Result (mg/kg)	Recovery (%)
DPL-69&70-2018 P matrix blank.lcd	< LOQ	-
DPL-69&70-2018 P PK1 0,010 mg-kg.lcd	0,012	116
DPL-69&70-2018 P PK1 0,10 mg-kg.lcd	0,119	119
DPL-69&70-2018 P matrix blank'.lcd	< LOQ	-
DPL-69&70-2018 P PK2 0,010 mg-kg.lcd	0,0093	92,8
DPL-69&70-2018 P PK2 0,10 mg-kg.lcd	0,113	113

All recovery values at fortification levels of 0,010 mg/g and 0,10 mg/kg comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev. 4.

In addition, the recovery values for PK2 0,010 mg/kg and PK2 0,10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure.

Conclusion:

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and $RSD \leq 20\%$ for average recovery.

The limit of quantification of the method was established at 0.012 mg/kg for oilseed rape pods and seeds. There were no interfering signals at retention time of analysed compound in examined control matrix. The validated analytical method used for determination of acetamiprid residues in oilseed rape (pods and seeds) fulfils criteria of acceptance restricted by SANCO/825/00 rev. 8.1 document

A 2.1.3.3.2 Study 2

Comments of zRMS:	<p>Analytical part of the B8177 (A 2.1.3.3.5) field study.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP).</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of quantification (LOQ) was 0.012 mg/kg.</p> <p>The presence of residues in OSR seed samples was found to be 0.093 mg/kg</p> <p>Max. storage interval between sampling and analysis: about 4 months. Stability studies cover 12 months for high oil matrices.</p> <p>The study is accepted.</p>
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Reference: KCA 6.3

Report	Determination of residue of acetamiprid in Oilseed rape (OSR) following foliar applications of APIS 200 SE Poland 2018, Grzegorz Paszek, 2018, DPL/67/2018
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC</p> <p>Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for annex II (part A, Section 4) and annex III (Part A section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/2000</p> <p>Guidance document on pesticide residue analytical methods SANCO/825/00, rev. 8.1; 16/11/2010</p> <p>Regulation (EU) 2017/626 of 31 March 2017 amending annexes II and III to regulation (EC) No 396/2005 of the European Parliament and of the council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos, and trifloxystrobin in or on certain products (Text with EEA relevance.)</p>
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Method:

LC-MS/MS Settings:

Instrument settings:

Liquid Chromatograph LCMS-8050 Shimadzu consists of:

Degazer DGU-20AXR

Two pumps LC-20ADXR (Nexera)

Autosampler SIL-20ACXR

Column oven CTO-20AC

Compresor, generator Peak Genius 1051

HPLC column – SynergiTM 4µm Fusian-RP 80 Å, 100 x 2 mm (Phenomenex)

Pumps:

Mode – Binary gradient

Total Flow – 0,25 ml/min

Mobile phase A – 5 mmol ammonium acetate solution in deionized water

Mobile Phase B – 5 mmol ammonium acetate solution in acetonitrile

A conc – 80%

B Conc – 20%

Cooler temp -4°C

Oven temp. 40 °C

Interface: ESI

Interface heater: on

Interface temp: 300 °C

DL temperature: 250 °C

Nebulizing Gas Flow: 3,00 L/min

Heating gas: on
Heating gas flow: 10,0 l/min
Heat block 400 °C
Drying gas: on
Drying gas flow: 10,0 L/min

The results for treated and untreated samples:

No	Country	Sponsor's sample identification	Commodity	Sample number given by the laboratory	Result [mg/kg]
1	Poland	B8177 PL1 / U0 / A	OSR (pods)	DPL/67/2018/01U	< LOQ
2	Poland	B8177 PL1 / T0 / A	OSR (pods)	DPL/67/2018/02T	2,80
3	Poland	B8177 PL1 / U14 / A	OSR (pods)	DPL/67/2018/03U	< LOQ
4	Poland	B8177 PL1 / T14/ A	OSR (pods)	DPL/67/2018/04T	0,71
5	Poland	B8177 PL1 / U28 / A	OSR (pods)	DPL/67/2018/05U	< LOQ
6	Poland	B8177 PL1 / T28 / A	OSR (pods)	DPL/67/2018/06T	0,51
7	Poland	B8177 PL1 / U33 / A	OSR (pods/seeds)	DPL/67/2018/07U	< LOQ
8	Poland	B8177 PL1 / T33 / A	OSR (pods/seeds)	DPL/67/2018/08T	0,80
9	Poland	B8177 PL1 / U45 / A	OSR (seeds)	DPL/67/2018/09U	< LOQ
10	Poland	B8177 PL1 / T45 / A	OSR (seeds)	DPL/67/2018/10T	0,093

Residues are not corrected for procedural recoveries;

Calculation based on unrounded values, **LOQ = 0,012 mg/kg**

Blank and fortification samples:

Quality control samples (seeds)

Sample Name	Result (mg/kg)	Recovery (%)
DPL-67 & 68-2018 S matrix blank.lcd	< LOQ	-
DPL-67 & 68-2018 S PK1 0,010 mg-kd.lcd	0,011	109
DPL-67 & 68-2018 S PK1 0,10 mg-kd.lcd	0,112	112
DPL-67 & 68-2018 S matrix blank'.lcd	< LOQ	-
DPL-67 & 68-2018 S PK2 0,010 mg-kd.lcd	0,010	104
DPL-67 & 68-2018 S PK2 0,10 mg-kd.lcd	0,108	108

Quality control samples (pods)

Sample Name	Result (mg/kg)	Recovery (%)
DPL-67 & 68-2018 P matrix blank.lcd	< LOQ	-
DPL-67 & 68-2018 P PK1 0,010 mg-kd.lcd	0,0080	80,0
DPL-67 & 68-2018 P PK1 0,10 mg-kd.lcd	0,120	120
DPL-67 & 68-2018 P matrix blank'.lcd	< LOQ	-
DPL-67 & 68-2018 P PK2 0,010 mg-kd.lcd	0,0091	91,3
DPL-67 & 68-2018 P PK2 0,10 mg-kd.lcd	0,104	104

All recovery values at fortification levels of 0,010 mg/g and 0,10 mg/kg comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev. 4.

In addition, the recovery values for PK2 0,010 mg/kg and PK2 0,10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure.

Conclusion:

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and $RSD \leq 20\%$ for average recovery.

The limit of quantification of the method was established at 0.012 mg/kg for oilseed rape pods and seeds. There were no interfering signals at retention time of analysed compound in examined control matrix. The validated analytical method used for determination of acetamiprid residues in oilseed rape (pods and

seeds) fulfils criteria of acceptance restricted by SANCO/825/00 rev. 8.1 document

A 2.1.3.3.3 Study 3

Comments of zRMS:	<p>Analytical part of the B8183 (A 2.1.3.3.4) field study.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP).</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of quantification (LOQ) was 0.012 mg/kg.</p> <p>The presence of residues in OSR seed samples was found to be 0.087 mg/kg</p> <p>Max. storage interval between sampling and analysis: about 4 months. Stability studies cover 12 months for high oil matrices.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Determination of residue of acetamiprid in Oilseed rape (OSR) following foliar applications of APIS 200 SE under field condition Northern France 2018, Grzegorz Paszek, 2018, DPL/68/2018
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC</p> <p>Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for annex II (part A, Section 4) and annex III (Part A section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/2000</p> <p>Guidance document on pesticide residue analytical methods SANCO/825/00, rev. 8.1; 16/11/2010</p> <p>Regulation (EU) 2017/626 of 31 March 2017 amending annexes II and III to regulation (EC) No 396/2005 of the European Parliament and of the council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos, and trifloxystrobin in or on certain products (Text with EEA relevance.)</p>
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Method:

LC-MS/MS Settings:

Instrument settings:

Liquid Chromatograph LCMS-8050 Shimadzu consists of:

Degazer DGU-20AXR

Two pumps LC-20ADXR (Nexera)

Autosampler SIL-20ACXR

Column oven CTO-20AC

Compresor, generator Peak Genius 1051

HPLC column – SynergiTM 4µm Fusian-RP 80 Å, 100 x 2 mm (Phenomenex)

Pumps:

Mode – Binary gradient

Total Flow – 0,25 ml/min

Mobile phase A – 5 mmol ammonium acetate solution in deionized water

Mobile Phase B – 5 mmol ammonium acetate solution in acetonitrile

A conc – 80%

B Conc – 20%

Cooler temp -4°C

Oven temp. 40 °C

Interface: ESI

Interface heater: on

Interface temp: 300 °C

DL temperature: 250 °C

Nebulizing Gas Flow: 3,00 L/min

Heating gas: on

Heating gas flow: 10,0 l/min

Heat block 400 °C

Drying gas: on

Drying gas flow: 10,0 L/min

The results for treated and untreated samples

No	Country	Sponsor's sample identification	Commodity	Sample number given by the laboratory	Result [mg/kg]
1	Northern France	B8183 MA1 / U0 / A	OSR (pods)	DPL/68/2018/01U	< LOQ
2	Northern France	B8183 MA1 / T0 / A	OSR (pods)	DPL/68/2018/02T	2,23
3	Northern France	B8183 MA1 / U14 / A	OSR (pods)	DPL/68/2018/03U	< LOQ
4	Northern France	B8183 MA1 / T14 / A	OSR (pods)	DPL/68/2018/04T	0,48
5	Northern France	B8183 MA1 / U28 / A	OSR (pods)	DPL/68/2018/05U	< LOQ
6	Northern France	B8183 MA1 / T28 / A	OSR (pods)	DPL/68/2018/06T	0,43
7	Northern France	B8183 MA1 / U33 / A	OSR (pods/seeds)	DPL/68/2018/07U	< LOQ
8	Northern France	B8183 MA1 / T33 / A	OSR (pods/seeds)	DPL/68/2018/08T	0,115
9	Northern France	B8183 MA1 / U45 / A	OSR (seeds)	DPL/68/2018/09U	< LOQ
10	Northern France	B8183 MA1 / T45 / A	OSR (seeds)	DPL/68/2018/10T	0,087

Residues are not corrected for procedural recoveries;
 Calculation based on unrounded values, LOQ = 0,012 mg/kg

Blank and fortification samples:

Quality control samples (seeds)

Sample Name	Result (mg/kg)	Recovery (%)
DPL-67 & 68-2018 S matrix blank.lcd	< LOQ	-
DPL-67 & 68-2018 S PK1 0,010 mg/kg.lcd	0,011	109
DPL-67 & 68-2018 S PK1 0,10 mg/kg.lcd	0,112	112
DPL-67 & 68-2018 S matrix blank'.lcd	< LOQ	-
DPL-67 & 68-2018 S PK2 0,010 mg/kg.lcd	0,010	104
DPL-67 & 68-2018 S PK2 0,10 mg/kg.lcd	0,108	108

Quality control samples (pods)

Sample Name	Result (mg/kg)	Recovery (%)
DPL-67 & 68-2018 P matrix blank.lcd	< LOQ	-
DPL-67 & 68-2018 P PK1 0,010 mg/kg.lcd	0,0080	80,0
DPL-67 & 68-2018 P PK1 0,10 mg/kg.lcd	0,120	120
DPL-67 & 68-2018 P matrix blank'.lcd	< LOQ	-
DPL-67 & 68-2018 P PK2 0,010 mg/kg.lcd	0,0091	91,3
DPL-67 & 68-2018 P PK2 0,10 mg/kg.lcd	0,104	104

All recovery values at fortification levels of 0,010 mg/g and 0,10 mg/kg comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev. 4.

In addition, the recovery values for PK2 0,010 mg/kg and PK2 0,10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure.

Conclusion:

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and RSD \leq 20% for average recovery.

The limit of quantification of the method was established at 0.012 mg/kg for oilseed rape pods and seeds. There were no interfering signals at retention time of analysed compound in examined control matrix. The validated analytical method used for determination of acetamiprid residues in oilseed rape (pods and

seeds) fulfils criteria of acceptance restricted by SANCO/825/00 rev. 8.1 document

A 2.1.3.3.4 Study 4

Comments of zRMS:	<p>The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 41 days before harvest.</p> <p>The study consisted of the field phase which was conducted under field conditions in Northern France.</p> <p>Samplings were performed at 0, 14, 26, 30 days after the application (DAA) and 41 DAA at BBCH 89 (at maturity of the grain).</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Northern France in 2018, Corinne Ertus, 2018, B8183
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Method and results:

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha. The study consisted of the field phase which was conducted under field conditions at one site in Northern France. One plot was treated once with APIS 200 SE at the application rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 41 days before harvest. One plot remained untreated. Samplings were performed at 0, 14, 26, 30 days after the application (DAA) and 41 DAA at BBCH 89 (at maturity of the grain). Samples generated during this study were sent for Acetamiprid residues analysis to SGS Polska Sp Z.o.o. laboratory.

Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	APIS 200 SE	T1	45 (±4) DBH	0.25 L/ha	50 g/ha	300 L/ha (±10%)

DBH: Days before harvest

Sampling Details

Decline curve trial

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	0 DAA	Pods	0.2 kg
S2	U, T	14 (±1) DAA	Pods	0.5 kg
S3	U, T	28 (±2) DAA	Pods	0.5 kg
S4	U, T	33 (±3) DAA	Pods or seeds*	0.5 kg
S5	U, T	45 (±4) DAA	Seeds	0.5 kg

DAA : Days after application

*If maturity was reached seeds had to be taken, if crop was still immature, pods had to be taken.

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8183 MA1	1	31/05/2018	0	69-71
	2	14/06/2018	14	75
	3	26/06/2018	26	75-85
	4	30/06/2018	30	87-89
	5	11/07/2018	41	89

DAA: Days after application

Application details:

PLOT	T
Application No.	1
Date	31/05/2018
Time	9:45
Application timing	41 Days before harvest
Growth stage (BBCH)	69-71
Air temperature (°C)	19.8
Soil temperature at 10 cm depth (°C)	17.5
Relative humidity (%)	75
Cloud cover (%)	100
Wind speed (m/s)	0
Wind direction	-
Soil condition	Damp
Leaf condition	Dry

Specific conditions of the application

Application No.	1
Average flow rate of the sprayer d_m (L/min)	3.87
Amount of test item mixed with water Q+ (g)	2.22
Prepared volume VOL+ (L)	2.50
Volume used Vact (L)	1.74
Target volume L (L/ha)	300
Actual volume sprayed La (L/ha) (1)	290
Target rate a.s. d (g/ha)	50.0
Actual rate a.s. da (g/ha) (2)	48.3
Deviation (%) from target rate (3)	-3.3

A 2.1.3.3.5 Study 5

Comments of zRMS:	<p>The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 39 days before harvest.</p> <p>The study consisted of the field phase which was conducted under field conditions in Poland.</p> <p>Samplings were performed at 0, 13, 27, 33 days after the application (DAA) and 39 DAA at BBCH 89 at maturity of the seeds.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Poland in 2018, Corinne Ertus, 2018, B8177
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Deviation(s):

Deviation No. 180711 Due to exceptional weather conditions (dry and warm), the crop reached the maturity earlier than usual. Then, the last sampling was done 39 days after application (DAA) instead of 45 (± 4) DAA as required in the study plan. The deviation has no impact because the sampling was done before the scheduled date; it is a worst case situation. Moreover, the deviation from the target date remained within the range of $\pm 25\%$ (Guidance Document SANCO 7525/VI/95 rev. 9).

Method and results:

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha. The study consisted of the field phase which was conducted under field conditions at one site in Poland. One plot was treated once with APIS 200 SE at the application rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 39 days before harvest (deviation No. 180711). One plot remained untreated. Samplings were performed at 0, 13, 27, 33 days after the application (DAA) and 39 DAA at BBCH 89 at maturity of the seeds (deviation No. 180711).

Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	APIS 200 SE	T1	45 (± 4) DBH	0.25 L/ha	50 g/ha	300 L/ha ($\pm 10\%$)

DBH: Days before harvest

Sampling Details

Decline curve trial

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	0 DAA	Pods	0.2 kg
S2	U, T	14 (± 1) DAA	Pods	0.5 kg
S3	U, T	28 (± 2) DAA	Pods	0.5 kg
S4	U, T	33 (± 3) DAA	Pods or seeds*	0.5 kg
S5	U, T	45 (± 4) DAA	Seeds	0.5 kg

DAA : Days after application

*If maturity was reached seeds had to be taken, if crop was still immature, pods had to be taken.

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8177 PL1	1	01/06/2018	0	72-73
	2	14/06/2018	13	76-77
	3	28/06/2018	27	81-82
	4	04/07/2018	33	85-86
	5	10/07/2018	39*	89

DAA: Days after application

Application details:

PLOT	T
Application No.	1
Date	01/06/2018
Time	9:05
Application timing	39 Days before harvest*
Growth stage (BBCH)	72-73
Air temperature (°C)	22.3
Soil temperature at 10 cm depth (°C)	19.5
Relative humidity (%)	56
Cloud cover (%)	15
Wind speed (m/s)	0
Wind direction	-
Soil condition	Dry
Leaf condition	Dry

Specific conditions of the application

Application No.	1
Average flow rate of the sprayer d_m (L/min)	5.18
Amount of test item mixed with water Q+ (g)	3.37
Prepared volume VOL+ (L)	3.80
Volume used Vact (L)	2.79
Target volume L (L/ha)	300
Actual volume sprayed La (L/ha) (1)	310
Target rate a.s. d (g/ha)	50.0
Actual rate a.s. da (g/ha) (2)	51.7
Deviation (%) from target rate (3)	+3.3

A 2.1.3.3.6 Study 6

Comments of zRMS:	<p>The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 27 days before harvest.</p> <p>The study consisted of the field phase which was conducted under field conditions in Northern France.</p> <p>Samplings were performed at 0, 14 days after the application (DAA) and 27 DAA at BBCH 89 (at maturity of the grain).</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Northern France in 2018, 2018, B8185
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Deviation(s):

Due to exceptional weather conditions (dry and warm), the crop reached the maturity earlier than usual. Both last samplings at 33 (± 3) and 45 (± 4) days after the application (DAA) were not collected. The third (and last) sampling was done at 27 DAA and at BBCH 89. Then, seeds were collected instead of pods. There is no impact on the study as the amount of residues are comparable with the amount of residues found in the other trials

Method and results:

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha. The study consisted of the field phase which was conducted under field conditions at one site in Northern France. One plot was treated once with APIS 200 SE at the application rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 27 days before harvest instead of 45 (± 4) days before harvest (see deviation 180626). One plot remained untreated. Samplings were performed at 0, 14 days after the application (DAA) and 27 DAA at BBCH 89 (at maturity of the grain). A deviation occurred during the field phase, the harvest was anticipated (see deviation 180626).

Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	APIS 200 SE	T1	45 (±4) DBH	0.25 L/ha	50 g/ha	300 L/ha (±10%)

DBH: Days before harvest

Sampling Details

Decline curve trial

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	0 DAA	Pods	0.2 kg
S2	U, T	14 (±1) DAA	Pods	0.5 kg
S3	U, T	28 (±2) DAA	Pods	0.5 kg
S4	U, T	33 (±3) DAA	Pods or seeds*	0.5 kg
S5	U, T	45 (±4) DAA	Seeds	0.5 kg

DAA : Days after application

*If maturity was reached seeds had to be taken, if crop was still immature, pods had to be taken.

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8185 BM1	1	30/05/2018	0	78
	2	13/06/2018	14	81
	3	26/06/2018	27	89
	4	*	-	-
	5	*	-	-

DAA: Days after application

Application details:

PLOT	T
Application No.	1
Date	30/05/2018
Time	15:20
Application timing	27 Days before harvest*
Growth stage (BBCH)	78
Air temperature (°C)	23.0
Soil temperature at 10 cm depth (°C)	18.9
Relative humidity (%)	66
Cloud cover (%)	80
Wind speed (m/s)	0.9
Wind direction	SW
Soil condition	Damp
Leaf condition	Dry

Specific conditions of the application

Application No.	1
Average flow rate of the sprayer d_m (L/min)	3.39
Amount of test item mixed with water Q+ (g)	1.77
Prepared volume VOL+ (L)	2.00
Volume used Vact (L)	1.14
Target volume L (L/ha)	300
Actual volume sprayed La (L/ha) (1)	317
Target rate a.s. d (g/ha)	50.0
Actual rate a.s. da (g/ha) (2)	52.8
Deviation (%) from target rate (3)	+5.7

*See deviation 180626

A 2.1.3.3.7 Study 7

Comments of zRMS:	<p>Analytical part of the B9219 CZ and B9220 DE field studies.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP).</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of quantification (LOQ) was 0.01 mg/kg, the limit of detection (LOD) was 0.003 mg/kg.</p> <p>The presence of residues in OSR seed samples from Czech Republic were found to be 0.015 mg/kg.</p>
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	<p>Max. storage interval between sampling and analysis: about 6 months. Stability studies cover 12 months for high oil matrices.</p> <p>The Applicant provided field part of the study conducted in Czech Republic only (Report No B9219).</p> <p>The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 48 days before harvest.</p> <p>Samplings were performed at 0 day before the application on untreated plot (plot U), 0 day after the application on treated plot (plot T) and at 14, 26, 33 and 48 days after the application on both treated and untreated plots.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3/03
Report	Final Report Determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Czech Republic and Germany in 2019, 2020, G. Paszek, Study No.: DPL/131/2019,
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC</p> <p>Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/2000</p> <p>Guidance document on pesticide residue analytical methods, SANCO/825/00 rev. 8.1, 16/11/2010</p> <p>Commission Regulation (EU) No 617/2014 of 3 June 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ethoxysulfuron, metsulfuron-methyl, acetamiprid, prosulfuron, rimsulfuron, sulfosulfuron and thifensulfuron-methyl in or on certain products Text with EEA relevance</p>
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Field phase

Reference:	KCA 6.3/09
Report	Generation of Field Specimens for the determination of Acetamiprid Residues in Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Czech Republic in 2019, C. ERTUS, 2019, Study code: B9219

Guideline(s): Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
 (Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
 Producer of commercial product: PUH Chemirol sp. z.o.o.
 Pesticide (s) (common name (s)): acetamiprid
 CCPR No (s):
 Trade name(s): APIS 200 SE
 Main uses e.g. insecticide, fungicide: Insecticide

Page: 1/1
 Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation (a)	F, G or I (b)	Pest or group of pests controlled (c)	Formulation		Method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (days) (min)	Application rate per treatment			PHI (days) (l)	Remarks (m)
			Type (d-f)	Conc. of a.s. (i)					g a.s./ha (max)	water L/ha	g a.s./hL (max)		
Oilseed rape	F	Biting and sucking insects	SE Suspo-emulsion	200 g/L	Medium volume spraying Overall spraying	-	1	-	50	300	16.7	45	-

Remarks:

- (a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes – GJFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of applications possible under practical conditions of use must be provided
- (l) PHI = Pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

The aim of the study is to evaluate the residue levels of acetamiprid Oilseed Rape Following Foliar application with APIS 200 SE under Field Conditions in Czech Republic and Germany in 2019. Samples will originate from the study performed in Czech Republic (B9219) and Germany (B9220). The results of the study will be used for registration of the plant protection product. Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.

THE RESULTS FOR TREATED AND UNTREATED SAMPLES

The following residues concentration was determined in the field samples analyzed on 30.07.2019:

**Table 11 Residue concentrations of acetamiprid detected in analyzed field samples
(STUDY NUMBER B9219 – Decline Trial No. B9219 CZ1)**

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	0 DAA*	B9219 CZ1/U0/A	OSR (pods)	DPL/131/2019/01U	< LOD
2		B9219 CZ1/T0/A	OSR (pods)	DPL/131/2019/02T	0,64
3	14 (±1) DAA	B9219 CZ1/U14/A	OSR (pods)	DPL/131/2019/03U	< LOD
4		B9219 CZ1/T14/A	OSR (pods)	DPL/131/2019/04T	0,39
5	28 (±2) DAA	B9219 CZ1/U28/A	OSR (pods)	DPL/131/2019/05U	< LOD
6		B9219 CZ1/T28/A	OSR (pods)	DPL/131/2019/06T	0,42
7	33 (±3) DAA	B9219 CZ1/U33/A	OSR (pods)	DPL/131/2019/07U	< LOD
8		B9219 CZ1/T33/A	OSR (pods)	DPL/131/2019/08T	0,38
9	45 (±4) DAA	B9219 CZ1/U45/A	OSR (seeds)	DPL/131/2019/09U	< LOD
10		B9219 CZ1/T45/A	OSR (seeds)	DPL/131/2019/10T	0,015

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, LOD = 0.003 mg/kg; LOQ = 0.010 mg/kg

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Four of the fortification samples (LOQ and 10 x LOQ) were run at each of analytical sequence (at the beginning and at the end of field samples) in order to ensure the active substance stability during the analytical method workflow.

Table 13 Quality control samples (seed)

Sample Name	Result [mg/kg]	Recovery [%]
s DPL-131-2019 matrix blank	< LOD	-
s DPL-131-2019 PK1 0,010 mg/kg	0,009	87,4
s DPL-131-2019 PK1 0,10 mg/kg	0,091	90,9
s DPL-131-2019 matrix blank'	< LOD	-
s DPL-131-2019 PK2 0,010 mg/kg	0,011	105
s DPL-131-2019 PK2 0,10 mg/kg	0,108	108

LOD = 0.003 mg/kg

Table 10 Quality control samples (plants)

Sample Name	Result [mg/kg]	Recovery [%]
p DPL-131-2019 matrix blank	< LOD	-
p DPL-131-2019 PK1 0,010 mg/kg	0,011	108
p DPL-131-2019 PK1 0,10 mg/kg	0,110	110
p DPL-131-2019 matrix blank'	< LOD	-
p DPL-131-2019 PK2 0,010 mg/kg	0,008	75,0
p DPL-131-2019 PK2 0,10 mg/kg	0,073	73,2

LOD = 0.003 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANCO/3029/99 and SANCO/825/00 rev. 8.1, 16/11/2010. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 2 hours, the duration of the chromatographic analysis was about 432 min for plants (7.2 h) and 288 min for seeds (4.8 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (14 h). Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The method was validated according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1, 16/11/2010 guidelines. The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of

quantification of the method was established at 0.010 mg/kg for seed and plants. There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of acetamiprid in OSR (plant and seeds) meets the criteria of SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines in terms of precision, accuracy and uncertainty.

A 2.1.3.3.8 Study 8

Comments of zRMS:	<p>Analytical part of the B7241 field studies.</p> <p>The study was performed with a different formulation (SE formulation instead of SC proposed in the intended GAP).</p> <p>Specimen extraction and determination of residues of acetamiprid were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection (extracts were analysed on the same day after extraction procedure).</p> <p>The limit of quantification (LOQ) was 0.012 mg/kg.</p> <p>The presence of residues in OSR seed samples found to be: 0.014 mg/kg, 0.045 mg/kg, and 2 x < LOQ</p> <p>Max. storage interval between sampling and analysis: about 4 months. Stability studies cover 12 months for high oil matrices.</p> <p>The Applicant provided field part of the study conducted in Czech Republic, North France, Poland and Hungary (Report No B7241).</p> <p>The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product APIS 200 SE (200 g/L acetamiprid) at the rate of 0.25 L/ha (50 g acetamiprid/ha). The application was made 36-42 days before harvest.</p> <p>Samplings were performed at 0, 14, 27-28, 31-34 and 36-42 days after the application.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3/02
Report	Final Report Determination of residues of acetamiprid in oilseed rape, 2017, A. Augustynek, Study Plan No.: DPL/03/2017,
Guideline(s):	<p>Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC</p> <p>Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414, SANCO/3029/99 rev. 4, 11/07/2000</p> <p>Guidance document on pesticide residue analytical methods, SANCO/825/00 rev. 8.1, 16/11/2010</p>

THE RESULTS FOR TREATED AND UNTREATED SAMPLES

The following residues concentration was determined in the field samples analyzed on 25.08.2017

No	Country	Sponsor's sample identification	Commodity	Sample number given by the laboratory	Result [mg/kg]
1	Poland	B7241 PL1 / U0 / A	oilseed rape - pods	DPL/03/2017/01U	< LOQ
2	Poland	B7241 PL1 / T0 / A	oilseed rape - pods	DPL/03/2017/02T	0.42
3	Poland	B7241 PL1 / U14 / A	oilseed rape - pods	DPL/03/2017/03U	< LOQ
4	Poland	B7241 PL1 / T14 / A	oilseed rape - pods	DPL/03/2017/04T	0.16
5	Poland	B7241 PL1 / U28 / A	oilseed rape - pods	DPL/03/2017/05U	< LOQ
6	Poland	B7241 PL1 / T28 / A	oilseed rape - pods	DPL/03/2017/06T	0.10
7	Poland	B7241 PL1 / U33 / A	oilseed rape - seeds	DPL/03/2017/07U	< LOQ
8	Poland	B7241 PL1 / T33 / A	oilseed rape - seeds	DPL/03/2017/08T	0.061
9	Poland	B7241 PL1 / U39 / A	oilseed rape - seeds	DPL/03/2017/09U	< LOQ
10	Poland	B7241 PL1 / T39 / A	oilseed rape - seeds	DPL/03/2017/10T	0.014
11	France	B7241 ND1 / U0 / A	oilseed rape - pods	DPL/03/2017/11U	< LOQ
12	France	B7241 ND1 / T0 / A	oilseed rape - pods	DPL/03/2017/12T	0.56
13	France	B7241 ND1 / U14 / A	oilseed rape - pods	DPL/03/2017/13U	< LOQ
14	France	B7241 ND1 / T14 / A	oilseed rape - pods	DPL/03/2017/14T	0.055
15	France	B7241 ND1 / U28 / A	oilseed rape - pods	DPL/03/2017/15U	< LOQ
16	France	B7241 ND1 / T28 / A	oilseed rape - pods	DPL/03/2017/16T	0.086
17	France	B7241 ND1 / U33 / A	oilseed rape - seeds	DPL/03/2017/17U	< LOQ
18	France	B7241 ND1 / T33 / A	oilseed rape - seeds	DPL/03/2017/18T	0.32
19	France	B7241 ND1 / U39 / A	oilseed rape - seeds	DPL/03/2017/19U	< LOQ
20	France	B7241 ND1 / T39 / A	oilseed rape - seeds	DPL/03/2017/20T	0.045

No	Country	Sponsor's field study number	Type of commodity group	Type of test sample	Result [mg/kg]
21	Hungary	B7241 HU1 / U0 / A	oilseed rape - pods	DPL/03/2017/21U	< LOQ
22	Hungary	B7241 HU1 / T0 / A	oilseed rape - pods	DPL/03/2017/22T	0.21
23	Hungary	B7241 HU1 / U14 / A	oilseed rape - pods	DPL/03/2017/23U	< LOQ
24	Hungary	B7241 HU1 / T14 / A	oilseed rape - pods	DPL/03/2017/24T	0.39
25	Hungary	B7241 HU1 / U28 / A	oilseed rape - seeds	DPL/03/2017/25U	< LOQ
26	Hungary	B7241 HU1 / T28 / A	oilseed rape - seeds	DPL/03/2017/26T	< LOQ
27	Hungary	B7241 HU1 / U33 / A	oilseed rape - seeds	DPL/03/2017/27U	< LOQ
28	Hungary	B7241 HU1 / T33 / A	oilseed rape - seeds	DPL/03/2017/28T	< LOQ
29	Hungary	B7241 HU1 / U39 / A	oilseed rape - seeds	DPL/03/2017/29U	< LOQ
30	Hungary	B7241 HU1 / T39 / A	oilseed rape - seeds	DPL/03/2017/30T	< LOQ
31	Czech Republic	B7241 CZ1 / U0 / A	oilseed rape - pods	DPL/03/2017/31U	< LOQ
32	Czech Republic	B7241 CZ1 / T0 / A	oilseed rape - pods	DPL/03/2017/32T	0.022
33	Czech Republic	B7241 CZ1 / U14 / A	oilseed rape - pods	DPL/03/2017/33U	< LOQ
34	Czech Republic	B7241 CZ1 / T14 / A	oilseed rape - pods	DPL/03/2017/34T	0.024
35	Czech Republic	B7241 CZ1 / U28 / A	oilseed rape - pods	DPL/03/2017/35U	< LOQ
36	Czech Republic	B7241 CZ1 / T28 / A	oilseed rape - pods	DPL/03/2017/36T	< LOQ
37	Czech Republic	B7241 CZ1 / U33 / A	oilseed rape - seeds	DPL/03/2017/37U	< LOQ
38	Czech Republic	B7241 CZ1 / T33 / A	oilseed rape - seeds	DPL/03/2017/38T	< LOQ
39	Czech Republic	B7241 CZ1 / U39 / A	oilseed rape - seeds	DPL/03/2017/39U	< LOQ
40	Czech Republic	B7241 CZ1 / T39 / A	oilseed rape - seeds	DPL/03/2017/40T	< LOQ

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, LOQ = 0,012 mg/kg

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at each of analytical sequence (at the beginning and at the end of field samples) in order to ensure the active substance stability during the analytical method workflow

Sample Name	Result (mg/kg)	Recovery (%)
DPL-03-2017 S matrix blank	< LOQ	-
DPL-03-2017 S PK1 0,010 mg/kg	0.012	102.1
DPL-03-2017 S PK2 0,010 mg/kg	0.013	109.8
DPL-03-2017 S PK1 0,10 mg/kg	0.115	98.9
DPL-03-2017 S PK2 0,10 mg/kg	0.105	90.8
DPL-03-2017 P matrix blank	< LOQ	-
DPL-03-2017 P PK1 0,010 mg/kg	0.0084	72.6
DPL-03-2017 P PK2 0,010 mg/kg	0.0087	74.6
DPL-03-2017 P PK1 0,10 mg/kg	0.109	93.8
DPL-03-2017 P PK2 0,10 mg/kg	0.126	108.8

S – seeds, P – pods; LOQ = 0.012 mg/kg

All recovery values at fortification levels of 0.010 mg/kg and 0.10 mg/kg comply with the standard acceptance criteria of the guidance document SANCO/3029/99 rev.4. In addition, the recovery values of PK2 0.010 mg/kg and PK2 0.10 mg/kg (in the range of 70 -120%) confirms the active substance stability during the analytical procedure.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70-120% and $RSD \leq 20\%$ for average recovery. The limit of quantification of the method was established at 0.01 mg/kg. There were no interfering signals at retention time of analysed compound in examined control matrix. The validated analytical method used for determination of acetamiprid in oilseed rape (pods and seeds) fulfills criteria of acceptance restricted by SANCO/825/00 rev.8.1 document..

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies submitted

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new studies submitted

A 2.1.5.2 Processing studies on a core set of representative processes

No new studies submitted

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.7 Other/Special Studies

A 2.1.7.1.1 Study 1

Comments of zRMS:	The study is accepted. Storage time of samples at $\leq -18^{\circ}\text{C}$ from sampling to extraction (days) – 35 days.
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Reference:	KCA 6.10
Report	Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Northern Europe in 2020, Lefebvre, C., C0280, Anadiag, France
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830, Rev.1 SANTE/11956/2016 rev. 9
Deviations:	Yes
GLP:	Yes

Acceptability: Yes

Objective of the study

The objective of the study was to determine the residue levels of acetamiprid in honey and pollen from bees foraging on white mustard following two foliar applications at flowering stage of the formulated product APIS 200 SE (200 g acetamiprid /L) together with the adjuvant Asysent+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase.
The study was conducted under semi-field conditions at one site in Northern Europe.
On the site, two tunnels covered with anti-insect nets were used: White mustard was grown under both tunnels. At flowering of the crop one tunnel was treated twice at 8 days interval with APIS 200 SE at the rate of 0.5 L product/ha (100 g acetamiprid /ha) and adjuvant Asysent+ at the rate of 0.35 L/ha. The second tunnel was kept untreated.
One honeybee colony was installed under each tunnel and bees foraging were restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of acetamiprid was analysed in the samples.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOPs.
Pollen: the amount required by the analytical method (2.5 g) was weighed from the matrix after mixing.
Honey: the sample was left about 2 hours at 4°C until thawing (not overnight: see deviation from the study plan from 26/10/2021).
The amount required by the analytical method (5 g) was weighed from the matrix after thawing and homogenisation.

Extraction

Water is added to the homogenized sample (5 g for honey, 2.5 g for pollen) which is then extracted with acetonitrile/acetic acid 99.9:0.1%. After addition of MgSO₄, NaCl, and buffering citrate salts (pH 5-5.5), the mixture is shaken intensively and centrifuged for phase separation. An aliquot of the organic phase is cleaned-up by:
- dispersive PSA addition.
- MgSO₄ addition.
Before analysis, the extract is diluted with the acetonitrile/acetic acid 99.9:0.1% mixture.
The analysis was done with LC-MS/MS.

Fortification and control samples

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Acetamiprid	MA1011-01	Honey	0.003	0.01
		Pollen	0.003	0.01

Deviations

Deviation No.28/10/2021-1:

The colonies were prepared 4 months before the beginning of the trial instead of 1-2 month before the beginning of the trial as required by the study plan due to organizational reason due to COVID-19 crisis.

This deviation has no impact on the study since the two selected colonies for the trial presented optimal and similar strength.

Deviation No.28/10/2021-2:

The rain data was recorded by the Principal Investigator at each monitoring event instead of every day as required by the study plan.

This deviation has no impact on the study since the daily precipitation was recorded by the weather station located at 190 m from the trial site and no rain occurred within one hour after each applications.

Deviation No.03/11/2021:

The strength of the colonies was not evaluated at the end of the trial, shortly after sampling of honey as required by the study plan, but three days before sampling of honey.

This deviation has no impact on the study as the honey maturity was reached at sampling time.

Results

The analytical results obtained are summarized in the table(s) below.

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Acetamiprid residues found (mg/kg)
C0280 01 01	C0280 PL1 / UH / A	-	Honey	-	< LOQ
C0280 01 03	C0280 PL1 / UP / A	-	Pollen	-	NDR
C0280 01 02	C0280 PL1 / TH / A	APIS 200 SE	Honey	Maturity	< LOQ
C0280 01 04	C0280 PL1 / TP / A	APIS 200 SE	Pollen	Maturity	1.48

< LOQ: Residues between LOD and LOQ

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANCO/3029/99, rev. 4 guidelines and SANTE/2020/12830, Rev.1 in terms of precision, accuracy and uncertainty.

A 2.1.7.1.2 Study 2

Comments of zRMS:	The study is accepted. Storage time of samples at ≤-18°C from sampling to extraction (days) – 19 days.
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Reference:

KCA 6.10

Report

Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Southern Europe in 2020, Lefebvre, C., C0281, Anadiag, France

Guideline(s):

Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
SANTE/2020/12830, Rev.1
SANTE/11956/2016 rev. 9

Deviations: Yes

GLP: Yes

Acceptability: Yes

Objective of the study

The objective of the study was to determine the residue levels of acetamiprid in honey and pollen from bees foraging on white mustard following two foliar applications at flowering stage of the formulated product APIS 200 SE (200 g acetamiprid /L) together with the adjuvant Asystent+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase.

The study was conducted under semi-field conditions at one site in Southern Europe.

On the site, two tunnels covered with anti-insect nets were used: White mustard was grown under both tunnels. At flowering of the crop one tunnel was treated twice at 8 days interval with APIS 200 SE at the rate of 0.5 L product/ha (100 g acetamiprid /ha) and adjuvant Asystent+ at the rate of 0.35 L/ha. The second tunnel was kept untreated.

One honeybee colony was installed under each tunnel and bees foraging were restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of acetamiprid was analysed in the samples.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOPs.

Pollen: the amount required by the analytical method (2.5 g or the amount available when < 2.5 g) was weighed from the matrix after homogenisation (no blending: see deviation No.26/10/2021).

Honey: the sample was left for about 2 hours at 4°C until thawing (not overnight: see deviation No.26/10/2021). The amount required by the analytical method (5 g) was weighed from the matrix after thawing and homogenisation.

Extraction

Water is added to the homogenized sample (5 g for honey, 2.5 g for pollen) which is then extracted with acetonitrile/acetic acid 99.9:0.1%. After addition of MgSO₄, NaCl, and buffering citrate salts (pH 5-5.5), the mixture is shaken intensively and centrifuged for phase separation. An aliquot of the organic phase is cleaned-up by:

- dispersive PSA addition,

- MgSO₄ addition.

Before analysis, the extract is diluted with the acetonitrile/acetic acid 99.9:0.1% mixture.

The analysis was done with LC-MS/MS.

Fortification and control samples

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Acetamiprid	MA1011-01	Honey	0.003	0.01
		Pollen	0.003	0.01

Deviations

Deviation No.19/08/2021:

- The weight of honey and pollen sampled was less than the minimum weight required by the study plan (100g for honey and 10g for pollen)

The amount of honey and pollen available was not sufficient at the time commercial maturity was reached.

This deviation has no impact on the study since the sampling is representative of the plot and the quantity of material is sufficient for analysis (untreated specimen from C0280 study was used to prepare spiked samples and matrix-matched calibration solutions).

Deviation No.14/10/2021-1:

Three colonies were prepared 4 months before the beginning of the trial instead of 4 colonies, 1-2 month before the beginning of the trial as required by the study plan because of an organizational reason due to COVID-19 crisis.

This deviation has no impact on the study since the two selected colonies for the trial presented optimal and similar strength.

Deviation No.14/10/2021-2:

The rain data was recorded by the Principal Investigator at each monitoring day instead of every day as required by the study plan.

This deviation has no impact on the study since no rain was recorded during the major part of the trial from application on 02/09/2020 to 18/09/2020. Moreover precipitation date was specified in the raw data if needed.

Deviation No. 14/10/2021-3:

The strength of the colonies was not evaluated at the end of the trial

This deviation has no impact on the study as the honey maturity was reached at sampling time.

Deviation No.27/10/2021

During the shipment from Anadiag Haguenau to the field station, the temperature of the test item APIS 200 SE and the adjuvant Asystent+ was above 30°C during about 12 hours with maximum at 34.6°C due to warm temperature in August. This deviation has no impact on the study since the sponsor has data to prove that the test item APIS 200 SE is stable after 14 days at 54°C

Results

The analytical results obtained are summarized in the table(s) below.

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Acetamiprid residues found (mg/kg)
C0281 01 01	C0281 EF1 / UH / A	-	Honey	-	NDR
C0281 01 03	C0281 EF1 / UP / A	-	Pollen	-	NDR
C0281 01 02	C0281 EF1 / TH / A	APIS 200 SE	Honey	Maturity	0.01
C0281 01 04	C0281 EF1 / TP / A	APIS 200 SE	Pollen	Maturity	4.21

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANCO/3029/99.

rev. 4 guidelines and SANTE/2020/12830, Rev.1 in terms of precision, accuracy and uncertainty.

A 2.1.7.1.3 Study 3

Comments of zRMS:	The study is accepted. Storage time of samples at $\leq -18^{\circ}\text{C}$ from sampling to extraction (days) -17 days.
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Reference: KCA 6.10

Report Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Southern Europe in 2021, Lefebvre, C., C1063, Anadiag, France

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
 SANTE/2020/12830, Rev.1
 SANTE/11956/2016 rev. 9

Deviations: Yes

GLP: Yes

Acceptability: Yes

Objective of the study

The objective of the study was to determine the residue levels of acetamiprid in honey and pollen from bees foraging on white mustard following two foliar applications at flowering stage of the formulated product APIS 200 SE (200 g acetamiprid /L) together with the adjuvant Asystent+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Southern Europe.

On the site, two tunnels covered with anti-insect nets were used: White mustard was grown under both tunnels. At flowering of the crop one tunnel was treated twice at 6 days interval with APIS 200 SE at the rate of 0.5 L product/ha (100 g acetamiprid /ha) and adjuvant Asystent+ at the rate of 0.35 L/ha. The second tunnel was kept untreated.

One honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of acetamiprid was analysed in the samples.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOPs.

The specimen of honey was allowed to thawed at $\approx +4^{\circ}\text{C}$. After mixing, the amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

After mixing of the specimen of pollen, the amount required by the analytical method (2.5 g) was weighed.

Extraction

Water is added to the homogenized sample (5 g for honey, 2.5 g for pollen) which is then extracted with acetonitrile/acetic acid 99.9:0.1%. After addition of MgSO₄, NaCl, and buffering citrate salts (pH 5-5.5), the mixture is shaken intensively and centrifuged for phase separation. An aliquot of the organic phase is cleaned-up by:

- dispersive PSA addition.
- MgSO₄ addition.

Before analysis, the extract is diluted with the acetonitrile/acetic acid 99.9:0.1% mixture.

The analysis was done with LC-MS/MS.

Fortification and control samples

LOD

The limit of detection (LOD) is expressed as the lowest matrix-matched calibration standard.

The limit of detection are:

Matrix	C _{LOD} * (ng/mL)	LOD (mg/kg) **
Honey	0.75	0.003 mg/kg
Pollen	0.38	0.003 mg/kg

* corresponds to the lowest matrix-matched calibration standard (after verification that peak height (signal)/peak height (noise) ratio ≥ 3).

**equivalent in samples in mg/kg (rounded to 30% of the LOQ).

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey and pollen.

Deviations

Deviation No.16/11/2021-1

The hives were set up in the tunnels 1h30 before 1st application instead 1 or 2 days before the 1st application as required by the study plan.

This deviation has no impact on the study since the application didn't affect the colonies and the hives were set up at flowering as required by the study plan.

Deviation No.16/11/2021-2

The weight of honey sampled was less than the minimum weight required by the study plan (100g)

The amount of honey available was not sufficient at the time commercial maturity was reached.

This deviation has no impact on the study since the sampling was representative of the plot and the quantity of material was sufficient for analysis.

Deviation No.16/11/2021-3

The shipment of the specimens was performed 14 days after last sampling instead of the day or the day after the sampling as required by the study plan.

The specimens were stored frozen below -18°C during all storage period at the field station and sent on time for analysis within 30 days after sampling. Shipment was done in good conditions.

Deviation No.16/11/2021-4

The rain data was recorded on site by the Principal Investigator at each monitoring event instead of every day as required by the study plan.

This deviation has no impact on the study since no rain was recorded during the major part of the trial from application on 08/06/2021 to 15/06/2021.

Deviation No.22/11/2021-1

The humidity of the honey was 20.9% for untreated specimen instead of < 20% as required in the study plan.

The trial had to be stopped according to the study plan because the flowering ended.

This deviation has no impact on the study as there is only a 0.9% deviation, thus the residue level should not be impacted. Moreover, no residue was expected for untreated plot.

The initial assessment of the colonies was performed just after introduction of the hives in the tunnels instead of prior to introduction in the tunnels as required by the study plan. The final assessment was

performed before honey sampling instead of after honey sampling as required in the study plan (but it was a mistake in the study plan).

This deviation has no impact on the study since the strength of the colonies would have been the same if the assessment had been made prior the introduction and it does not make sense to evaluate the strength of the colonies after honey sampling.

Results

The analytical results obtained are summarized in the table(s) below.

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Acetamiprid residues found (mg/kg)
C1063 01 01	C1063 PH1 / UH / A	-	Honey	-	NDR
C1063 01 02	C1063 PH1 / TH / A	APIS 200 SE	Honey	Maturity	0.09
C1063 01 03	C1063 PH1 / UP / A	-	Pollen	-	NDR
C1063 01 04	C1063 PH1 / TP / A	APIS 200 SE	Pollen	Maturity	0.66

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANCO/3029/99, rev. 4 guidelines and SANTE/2020/12830, Rev.1 in terms of precision, accuracy and uncertainty.

A 2.1.7.1.4 Study 4

Comments of zRMS:	The study is accepted. Storage time of samples at ≤-18°C from sampling to extraction (days) – 25 days.
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Reference: KCA 6.10

Report: Determination of Acetamiprid Residues in Honey and Pollen Following Foliar applications with APIS 200 SE on White Mustard under semi-field Conditions in Northern Europe in 2021, Lefebvre, C., C1064, Anadiag, France

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
 SANTE/2020/12830, Rev.1
 SANTE/11956/2016 rev. 9

Deviations: Yes

GLP: Yes

Acceptability: Yes

Objective of the study

The objective of the study was to determine the residue levels of acetamiprid in honey and pollen from bees foraging on white mustard following two foliar applications at flowering stage of the formulated product APIS 200 SE (200 g acetamiprid /L) together with the adjuvant Asysent+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Northern Europe.

On the site, two tunnels covered with anti-insect nets were used: white mustard was grown under both tunnels. At flowering of the crop one tunnel was treated twice at 7 days interval with APIS 200 SE at the rate of 0.5 L product/ha (100 g acetamiprid /ha) and adjuvant Asysent+ at the rate of 0.35 L/ha. The second tunnel was kept untreated.

One honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of acetamiprid was analysed in the samples.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOPs.

The specimen of honey was allowed to thawed at $\approx +4^{\circ}\text{C}$. After mixing, the amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

After mixing of the specimen of pollen, the amount required by the analytical method (2.5 g) was weighed.

Extraction

Water is added to the homogenized sample (5 g for honey, 2.5 g for pollen) which is then extracted with acetonitrile/acetic acid 99.9:0.1%. After addition of MgSO_4 , NaCl, and buffering citrate salts (pH 5-5.5), the mixture is shaken intensively and centrifuged for phase separation. An aliquot of the organic phase is cleaned-up by:

- dispersive PSA addition,
- MgSO_4 addition.

Before analysis, the extract is diluted with the acetonitrile/acetic acid 99.9:0.1% mixture.

The analysis was done with LC-MS/MS.

Fortification and control samples

LOD

The limit of detection (LOD) is expressed as the lowest matrix-matched calibration standard.

The limit of detection are:

Matrix	C_{LOD}^* (ng/mL)	LOD (mg/kg) **
Honey	0.75	0.003 mg/kg
Pollen	0.38	0.003 mg/kg

* corresponds to the lowest matrix-matched calibration standard (after verification that peak height (signal)/peak height (noise) ratio ≥ 3).

**equivalent in samples in mg/kg (rounded to 30% of the LOQ).

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey and pollen.

Deviations

Deviation No. 15/06/2021

The weight of honey sampled was less than the mass required by the study plan (100g)

The amount of honey and pollen available was not sufficient at the time commercial maturity was reached. This deviation has no impact on the study since the sampling was representative of the plot and the quantity of material was sufficient for analysis.

Deviation No. 19/10/2021-1

Colonies were prepared on 31/05/2021 and set in the tunnels on 01/06/2021 whereas the study plan required to prepare the colonies 1-2 months before the beginning of the trial as required by the study plan. This deviation has no impact on the study since it didn't affect the strength of the colony, the two selected colonies presented optimal and similar strength.

Deviation No. 19/10/2021-2

The rain data was recorded by the Principal Investigator at each monitoring instead of every day as required by the study plan. This deviation has no impact on the study since the total amount of precipitation was recorded at applications time (see weather data from Ommeray weather station located at ≈ 3 km from the trial)

Deviation No. 15/11/2021:

The hives were composed of 2 empty frames and 5 food frames instead of 3-5 empty frames and 1-3 honey/pollen frames as required in the study plan. The organization was adapted to the advice of the beekeeper to have a better honey production.

The plots size (U and T) was 168 m² instead of minimum 180 m² as required by the study plan because the actual length of one of the tunnels did not allow the trial to be conducted in a 180 m² plot.

Due to the availability of Anadiag truck driver, the shipment of the specimens was performed 9 days after sampling instead of the day or the day after the sampling as required by the study plan.

This deviation has no impact on the study since the amount of honey and pollen sampled was enough for analysis, any minimum plot size is required by SANTE/11956/2016 rev.9 and the analysis was performed within 30 days after sampling.

Results

The analytical results obtained are summarized in the table(s) below.

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Acetamiprid residues found (mg/kg)
C1064 01 01	C1064 MA1 / UH / A	-	Honey	-	NDR
C1064 01 02	C1064 MA1 / TH / A	APIS 200 SE	Honey	Maturity	0.05
C1064 01 03	C1064 MA1 / UP / A	-	Pollen	-	NDR
C1064 01 04	C1064 MA1 / TP / A	APIS 200 SE	Pollen	Maturity	0.07

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD \leq 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANCO/3029/99, rev. 4 guidelines and SANTE/2020/12830, Rev.1 in terms of precision, accuracy and uncertainty.

Field phase summary- Residues in honey

Country (city) Year Trial No.	Commodity	Application					Residues (pyrimethanil)		
		Number of applications	Application rate kg a.i./ha	L/ha	Growth stage (BBCH)	Date of applications	Commodity growth stage (BBCH)	DALA (days)	mg/kg
Poland 2020 C0280 PL1	White mustard	2	0.1012 0.0991	405 396	BBCH 64 BBCH 67	26/08/2020 03/09/2020	N/A	4	< LOQ
France 2020 C0281 EF1	White mustard	2	0.0941 0.0981	282 294	BBCH 63 BBCH 65	2/09/2020 10/09/2020	N/A	13	0.01
France 2021 C1063 PH1	White mustard	2	0.1003 0.1003	301 301	BBCH 65 BBCH 67	8/06/2021 14/06/2021	N/A	8	0.09
France 2021 C1064 MA1	White mustard	2	0.1022 0.1056	307 317	BBCH 65 BBCH 67	2/06/2021 9/06/2021	N/A	5	0.05

A 2.2 Deltamethrin

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

No new studies submitted

A 2.2.1.1.2 Storage stability of residues in animal products

No new studies submitted

A 2.2.2 Nature of residues in plants, livestock and processed commodities

A 2.2.2.1 Nature of residue in plants

No new studies submitted

A 2.2.2.1.1 Nature of residue in primary crops

No new studies submitted

A 2.2.2.1.2 Nature of residue in rotational crops

No new studies submitted

A 2.2.2.1.3 Nature of residues in processed commodities

No new studies submitted

A 2.2.2.2 Nature of residues in livestock

No new studies submitted

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Spring barley

Spring barley summary:

Report-No. Location	Commodity/Variety	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i/ha	Water l/ha	Kg a.i./hl						
B7144 N1, France, Hauts de France	Spring Barley / IRINA	1) 16/03/2017 2) 2) 17/07/2017	0.0055	218	0.0025	16/06/2017	BBCH 75	Grain	0.0096	31	LOQ = 0.01 mg/kg
								Straw	0.15		
B7144 HU1, Hungary, Komarom Esztegröm County	Spring Barley / SCARLETT	1) 13/03/2017 2) 13/07/2017	0.0053	319	0.00166	14/06/2017	BBCH 75	Grain	0.018	29	LOQ = 0.01 mg/kg
								Straw	0.10		

B7144 PL1, Poland, Łódzkie	Spring Barley / SOLDO	1) 28/03/2017 2) 29/07/2017	0.0051	405	0.00126	27/06/2017	BBCH 75	Grain	0.0086	32	LOQ = 0.01 mg/kg
								Straw	0.052		
B7144 CZ1, Czech Republic, Hradec Kralowe	Spring Barley / AZIT	1) 31/03/2017 2) 08/08/2017	0.0048	290	0.00165	12/07/2017	BBCH 75	Grain	0.016	27	LOQ = 0.01 mg/kg
								Straw	0.11		

A 2.2.3.1.1 Study 1

Comments of zRMS:	The study has not been evaluated and does not support the proposed use on wheat. According to the SANTE/2019/12752 Rev01, barley study results can be extrapolated to wheat before forming of the edible part. In case of cereals "before forming of the edible part" must be intended as before stage BBCH 51. Proposed in intended GAP BBCH for wheat and triticale is 37-75.
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Reference:	KCA 6.3
Report	DETERMINATION OF RESIDUES OF DELTAMETHRIN IN SPRING BARLEY APPLIED AS "DELTAMETHRIN 100 SC" IN NORTHERN EUROPE IN 2017, 2018, Joanna Kicińska, ZBBZ-2017/06/DPL/1
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention times of analyte in extracts corresponds to that of the calibration standards with a tolerance of $< \pm 0.1$ min. Also, confirmation ratios for Deltamethrin in all samples were within ± 30 % of the average found for the standards. No significant interference above 30 % of LOQ was detected in any of the reagent blanks or control specimen extracts for Spring Barley matrix, so that a highly level of selectivity was demonstrated and an additional confirmatory method is not necessary.

Matrix effects:

Matrix effects on the detection of Deltamethrin in extracts of Spring Barley were found to be significant (> 20 %). Thus matrix-matched standards were used for quantification.

Linearity

The correlation between the injected concentration of analyte standard and detector response was demonstrated to be linear by single determination of matrix-matched calibration standards at seven concentration levels ranging from 0.0015 $\mu\text{g/mL}$ to 0.2 $\mu\text{g/mL}$ for Spring Barley (ears, grain) and nine concentration levels ranging from 0.0005 $\mu\text{g/mL}$ to 0.2 $\mu\text{g/mL}$ for Spring Barley (rest of plants and straw). Those ranges correspond from 0.003 mg/kg to 0.4 mg/kg for Spring Barley (ears, grain) and 0.002 mg/kg to 0.8 mg/kg for Spring Barley (rest of plants and straw) thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration level detected in samples. The calibration curves obtained for both ion mass transitions of Deltamethrin were linear with the coefficients of correlation (R) greater than 0.99. Linear regression was performed with 1/x weighting.

Accuracy and precision:

Accuracy was determined by fortification of control samples with known amounts of the reference item and subsequent determination of the recoveries when applying the extraction procedure. Precision was determined by repeatability (relative standard deviation – RSD). The mean recovery values at the fortification levels of 0.01 mg/kg and 0.1 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANCO/825/00 rev. 8.1 and SANCO/3029/99, rev. 4. All precision values at the fortification levels of 0.01 mg/kg and 0.1 mg/kg for both ion mass transitions were < 20%.

Summary of recovery results

Analyte	Matrix	Fortification Level (mg/kg)	Mean Recovery (%)	RSD (%)	n	Overall Mean Recovery (%)	Overall RSD (%)
Deltamethrin	Ion Mass Transition 252.9→172.0 (Quantification)						
	Spring Barley (ears)	0.01*	93	3.6	5	90	4.0
		0.1	88	1.0	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Spring Barley (ears)	0.01*	95	3.8	5	91	4.9
		0.1	88	1.0	5		
	Ion Mass Transition 252.9→172.0 (Quantification)						
	Spring Barley (rest of plants)	0.01*	96	3.8	5	91	6.8
		0.1	85	2.2	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Spring Barley (rest of plants)	0.01*	92	2.3	5	88	6.1
		0.1	83	4.3	5		
	Ion Mass Transition 252.9→172.0 (Quantification)						
	Spring Barley (straw)	0.01*	78	3.0	5	79	3.2
		0.1	80	2.7	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Spring Barley (straw)	0.01*	77	7.2	5	78	5.4
		0.1	80	2.0	5		
	Ion Mass Transition 252.9→172.0 (Quantification)						
	Spring Barley (grain)	0.01*	100	7.6	5	102	6.2
		0.1	105	3.9	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Spring Barley (grain)	0.01*	102	7.4	5	103	5.6
		0.1	105	3.7	5		

*-Limit of quantification, defined by the lowest validated fortification level

Limit of Quantification (LOQ) and Limit of Detection (LOD):

The limit of quantification (LOQ) is the lowest validated fortification level and was thus successfully established at 0.01 mg/kg for both ion mass transitions of Deltamethrin in Spring Barley matrix. The limit of detection (LOD) for Deltamethrin was set at 0.002 mg/kg for tested matrix, which is < 30% of the LOQ. The limit of detection (LOD) for Deltamethrin was set at 0.003 mg/kg for tested matrix, which is < 30% of the LOQ.

Results obtained for the analysis of Spring Barley:

Summary of results from residue analysis of Spring Barley

Crop (matrix)	Field trial sample code – description / Treatment (U-Untreated, T-Treated)	Lab. Sample ID	Rep.	Mean Residues of Deltamethrin [mg/kg]
Spring Barley (ears)	B7144 ND1 / U1G / A	17/06/DPL/1/1	3	< LOD
	B7144 ND1 / T1G / A	17/06/DPL/1/2	3	<u>0.044</u>
Spring Barley (rest of plants)	B7144 ND1 / U1S / A	17/06/DPL/1/3	3	< LOD
	B7144 ND1 / T1S / A	17/06/DPL/1/4	3	<u>0.062</u>
Spring Barley (ears)	B7144 ND1 / U2G / A	17/06/DPL/1/5	3	< LOD
	B7144 ND1 / T2G / A	17/06/DPL/1/6	3	<u>0.049</u>
Spring Barley (rest of plants)	B7144 ND1 / U2S / A	17/06/DPL/1/7	3	< LOD
	B7144 ND1 / T2S / A	17/06/DPL/1/8	3	<u>0.057</u>
Spring Barley (straw)	B7144 ND1 / UHS / A	17/06/DPL/1/9	3	< LOD
	B7144 ND1 / THS / A	17/06/DPL/1/10	3	<u>0.15</u>
Spring Barley (grain)	B7144 ND1 / UHG / A	17/06/DPL/1/11	3	< LOD
	B7144 ND1 / THG / A	17/06/DPL/1/12	3	<u>0.0096</u>
Spring Barley (ears)	B7144 HU1 / U1G / A	17/06/DPL/1/13	3	<u>0.0024</u>
	B7144 HU1 / T1G / A	17/06/DPL/1/14	3	<u>0.10</u>
Spring Barley (rest of plants)	B7144 HU1 / U1S / A	17/06/DPL/1/15	3	<u>0.0028</u>
	B7144 HU1 / T1S / A	17/06/DPL/1/16	3	<u>0.033</u>
Spring Barley (ears)	B7144 HU1 / U2G / A	17/06/DPL/1/17	3	<u>0.0021</u>
	B7144 HU1 / T2G / A	17/06/DPL/1/18	3	<u>0.099</u>
Spring Barley (rest of plants)	B7144 HU1 / U2S / A	17/06/DPL/1/19	3	<u>0.0042</u>
	B7144 HU1 / U2S / A	17/06/DPL/1/20	3	<u>0.045</u>
Spring Barley (straw)	B7144 HU1 / UHS / A	17/06/DPL/1/21	3	< LOD
	B7144 HU1 / THS / A	17/06/DPL/1/22	3	<u>0.10</u>
Spring Barley (grain)	B7144 HU1 / UHG / A	17/06/DPL/1/23	3	< LOD
	B7144 HU1 / THG / A	17/06/DPL/1/24	3	<u>0.018</u>

Summary of results from residue analysis of Spring Barley (cont.)

Crop (matrix)	Field trial sample code – description / Treatment (U-Untreated, T-Treated)	Lab. Sample ID	Rep.	Mean Residues of Deltamethrin [mg/kg]
Spring Barley (ears)	B7144 PL1 / U1G / A	17/06/DPL/1/25	3	< LOD
	B7144 PL1 / T1G / A	17/06/DPL/1/26	3	<u>0.045</u>
Spring Barley (grain)	B7144 PL1 / U1S / A	17/06/DPL/1/27	3	< LOD
	B7144 PL1 / B1S / A	17/06/DPL/1/28	3	<u>0.035</u>
Spring Barley (ears)	B7144 PL1 / U2G / A	17/06/DPL/1/29	3	< LOD
	B7144 PL1 / T2G / A	17/06/DPL/1/30	3	<u>0.064</u>
Spring Barley (rest of plants)	B7144 PL1 / U2S / A	17/06/DPL/1/31	3	< LOD
	B7144 PL1 / T2S / A	17/06/DPL/1/32	3	<u>0.046</u>
Spring Barley (straw)	B7144 PL1 / UHS / A	17/06/DPL/1/33	3	< LOD
	B7144 PL1 / THS / A	17/06/DPL/1/34	3	<u>0.052</u>
Spring Barley (grain)	B7144 PL1 / UHG / A	17/06/DPL/1/35	3	< LOD
	B7144 PL1 / THG / A	17/06/DPL/1/36	3	<u>0.0086</u>
Spring Barley (ears)	B7144 CZ1 / U1G / A	17/06/DPL/1/37	3	< LOD
	B7144 CZ1 / T1G / A	17/06/DPL/1/38	3	<u>0.059</u>
Spring Barley (rest of plants)	B7144 CZ1 / U1S / A	17/06/DPL/1/39	3	< LOD
	B7144 CZ1 / T1S / A	17/06/DPL/1/40	3	<u>0.14</u>
Spring Barley (ears)	B7144 CZ1 / U2G / A	17/06/DPL/1/41	3	< LOD
	B7144 CZ1 / T2G / A	17/06/DPL/1/42	3	<u>0.029</u>
Spring Barley (rest of plants)	B7144 CZ1 / U2S / A	17/06/DPL/1/43	3	< LOD
	B7144 CZ1 / T2S / A	17/06/DPL/1/44	3	<u>0.098</u>
Spring Barley (straw)	B7144 CZ1 / UHS / A	17/06/DPL/1/45	3	< LOD
	B7144 CZ1 / THS / A	17/06/DPL/1/46	3	<u>0.11</u>
Spring Barley (grain)	B7144 CZ1 / UHG / A	17/06/DPL/1/47	3	< LOD
	B7144 CZ1 / THG / A	17/06/DPL/1/48	3	<u>0.016</u>

Conclusion:

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Deltamethrin, and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for Deltamethrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Spring Barley (rest of plants and straw) and 0.003 mg/kg for Spring Barley (ears and grain). It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (and SANCO/825/00, rev. 8.1. SANCO/3029/99, rev. 4) and is, applicable as enforcement and data generation method for determination of Deltamethrin in Spring Barley after application of and “DELTAMETHRIN 100 SC”

A 2.2.3.1.2 Study 2

Comments of zRMS:	The study has not been evaluated and does not support the proposed use on wheat. According to the SANTE/2019/12752 Rev01, barley study results can be extrapolated to wheat before forming of the edible part. In case of cereals "before forming of the edible part" must be intended as before stage BBCH 51. Proposed in intended GAP BBCH for wheat and triticale is 37-75.
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Reference:	KCA 6.3
Report	Generation of field specimens for the determination of deltamethrin residues in spring barley following foliar application with DELTAMETHRIN 100 SC under field conditions in Northern Europe in 2017, 2017, Corinne Ertus, B7144
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to generate specimens of spring barley raw agricultural commodity after one foliar application of the formulated product DELTAMETHRIN 100 SC (100g deltamethrin/L) at the rate of 0.05 L/ha.

The study consisted of one single phase: the field phase.

The study was conducted under field conditions at 4 sites in northern Europe. All the trials were sampled three times to monitor the decline of residues between the treatment and the harvest. In each trial one plot was treated one with DELTAMETHRIN 100 SC at the application rate of 0.05 L F.P./ha (equivalent to 5g/ha as deltamethrin). The application of DELTAMETHRIN 100 SC was made at BBCH 75 and 30 +/- 3 days before the harvest.

One plot remained untreated.

In each trail, sampling was performed at BBCH 83, at BBCH 85-87 and at maturity of the crop (30 +/- 3 days after the application)

Samples generated during this study were sent to be analysed to INSTYTUT OGRODNICTWA

Deviation

Deviation No. 170828

Trial B7144 CZ1:

The samples were shipped to the wrong laboratory. Mistake in the delivery addressee. The specimens were kept frozen by the first delivered laboratory and shipped under dry ice conditions by the Field Principal investigator herself to the right laboratory. Dry ice was still present at receipt.

Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of active substance	Spray volume
U	Untreated	--	--	--	--	--
T	DELTAMETHRIN 100 SC	T1	BBCH 75 and 30 (± 3) DBH	0.05 L / ha	5 g deltamethrin /ha	200 - 400 L/ha ($\pm 10\%$)

DBH: Days before harvest

Sampling Details

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	BBCH 83	Rest of plants Ears	0.5 kg from ≥ 12 plants 1.5 kg
S2	U, T	BBCH 85 - 87	Rest of plants Ears	0.5 kg from ≥ 12 plants 1.5 kg
S3	U, T	BBCH 89 – 97 (normal harvest) and 30 (± 3) DAA	Straw Grain	0.5 kg from ≥ 12 plants 1 kg

DAA: Days after application

Application data

Summary of the actual application(s) data

Trial No.	Plot	Application No.	a.s. rate (g/ha)	Deviation from the intended application rate (%)	Spray volume (L/ha)	Date	Growth stage (BBCH)
B7144 ND1	T	1	5.5	+9.0	218	16/06/2017	75
B7144 HU1	T	1	5.3	+6.3	319	14/06/2017	75
B7144 PL1	T	1	5.1	+1.3	405	27/06/2017	75
B7144 CZ1	T	1	4.8	-3.3	290	12/07/2017	75

Sampling summary:

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B7144 ND1	1	30/06/2017	14	83
	2	07/07/2017	21	85
	3	17/07/2017	31	89
B7144 HU1	1	22/06/2017	8	83
	2	27/06/2017	13	87
	3	13/07/2017	29	89
B7144 PL1	1	17/07/2017	20	83
	2	24/07/2017	27	85-87
	3	29/07/2017	32	89
B7144 CZ1	1	19/07/2017	7	83
	2	25/07/2017	13	87
	3	08/08/2017	27	89-92

DAA: Days after application

zRMS comments:

Comparison of intended and critical EU GAPs for deltamethrin:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (g a.s./ha)	PHI (days)
Wheat (code 0500090)				
cGAP EU EFSA Journal 2015;13(11):4309	n.a.	3 (14 days)	7.5	30
Intended GAP (major use No 3, wheat)	BBCH 37-75	1	4.8	n/a
Intended GAP (major use No 4, triticale)	BBCH 37-75	1	4.8	n/a

A 2.2.3.2 Winter Wheat

Winter wheat summary (It is not indicated whether trans- and alpha-R-deltamethrin is determined by this method, therefore the results are informative only):

Report- No. Location	Commodity/Variety	Plot	Date of: 1) Sowing or planting 2) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Mean Residues (mg/kg)	PHI (days)	Remarks
				Kg a.i/ha	Water l/ha	Kg a.i./hl						
B7143 ND1, France, Hauts de France	Winter Wheat / BODECOR	B	1) 28/10/2016 2) 18/07/2017	0.0053	210	0.0025	31/05/2017	BBCH 59	Grain	NDR	48	LOQ = 0.01 mg/kg
									Straw	0.0177		
		C		0.0054	215	0.0025	15/06/2017	BBCH 79	Grain	NDR	33	
									Straw	0.247		

B7143 HU1, Hungary, Komarom Esztegro m County	Winter Wheat / GK BERENY	B	1) 19/10/2016 2) 19/07/2017	0.005 4	325	0.0016 6	20/05/201 7	BBCH 59	Grain	NDR	60	LOQ = 0.01 mg/kg			
B7143 PL1, Poland, Łódzkie	Winter Wheat / TONACJA	B	1) 14/10/2016 2) 04/08/2017	0.005	298	0.0016 6	09/06/201 7	BBCH 79	Grain	NDR	56	LOQ = 0.01 mg/kg			
B7143 CZ1, Czech Republic, Hradec Kralowe	Winter Wheat / HERMANN	B	1) 14/11/2016 2) 01/08/2017	0.005 5	327	0.0016 6	05/06/201 7	BBCH 59	Grain	NDR	57	LOQ = 0.01 mg/kg			

Plot B: Treated with DELCAPS 050 CS

Plot C: treated with DELTAMETHRIN 100 SC

A 2.2.3.2.1 Study 1

Comments of zRMS:	<p>The study covers only the analytical part. The relevant field part of the study is described in report No B7143.</p> <p>The objective of this study was to determine the decline and the magnitude of residues of deltamethrin in winter wheat samples taken from the field trials following application of DELCAPS 050 CS and DELTAMETHRIN 100 SC.</p> <p>In accordance with the proposed GAP, part of the study regarding the use of DELTAMETHRIN 100 SC was performed and only the results from this part of the study can be included in the assessment.</p> <p>The general principles of the analytical procedure were based on the normalized method EN 15662:2008. Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS).</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for Deltamethrin. The limit of detection (LOD) was 0.002 mg/kg for wheat (rest of plants and straw) and 0.003 mg/kg for wheat (ears and grain).</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>It is not indicated whether trans- and alpha-R-deltamethrin is determined by this method, therefore the results are informative only.</p>
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Reference:	KCA 6.3
Report	DETERMINATION OF RESIDUES OF DELTAMETHRIN IN WINTER WHEAT APPLIED AS “DELCAPS 050 CS” AND “DELTAMETHRIN 100 SC” IN NORTHERN EUROPE IN 2017, 2018, Joanna Kicińska, ZBBZ-2017/05/DPL/1
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Directive 96/46/EC Amending Directive 91/414/EEC, Annex II, section 4 of Part A EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

Quantification was performed by use of highly selective gas chromatography coupled with tandem mass spectrometry (GC-MS/MS). Two selected ion mass transitions were evaluated in order to demonstrate that the method achieves a high level of selectivity. The retention times of analyte in extracts corresponds to that of the calibration standards with a tolerance of ± 0.1 min. Also, confirmation ratios for Deltamethrin in all samples were within ± 30 % of the average found for the standards. No significant interference above 30 % of LOQ was detected in any of the reagent blanks or control specimen extracts for Winter Wheat matrix, so that a highly level of selectivity was demonstrated and an additional confirmatory method is not necessary.

Matrix Effects:

Matrix effects on the detection of Deltamethrin in extracts of Winter Wheat were found to be significant

(> 20 %). Thus matrix-matched standards were used for quantification.

Linearity:

The correlation between the injected concentration of analyte standard and detector response was demonstrated to be linear by single determination of matrix-matched calibration standards at seven concentration levels ranging from 0.0015 µg/mL to 0.2 µg/mL for Winter Wheat (ears, grain) and nine concentration levels ranging from 0.0005 µg/mL to 0.2 µg/mL for Winter Wheat (rest of plants and straw). Those ranges correspond from 0.003 mg/kg to 0.4 mg/kg for Winter Wheat (ears, grain) and 0.002 mg/kg to 0.8 mg/kg for Winter Wheat (rest of plants and straw) thus covers the range from no more than 30 % of the LOQ and at least + 20 % of the highest analyte concentration level detected in samples. The calibration curves obtained for both ion mass transitions of Deltamethrin were linear with the coefficients of correlation (R) greater than 0.99. Linear regression was performed with 1/x weighting.

Accuracy and Precision:

Accuracy was determined by fortification of control samples with known amounts of the reference item and subsequent determination of the recoveries when applying the extraction procedure. Precision was determined by repeatability (relative standard deviation – RSD). The mean recovery values at the fortification levels of 0.01 mg/kg and 0.1 mg/kg for both ion mass transitions were all in the range 70 – 110 % and thus comply with the standard acceptance criteria of the guidance document SANCO/825/00 rev. 8.1 and SANCO/3029/99, rev. 4. All precision values at the fortification levels of 0.01 mg/kg and 0.1 mg/kg for both ion mass transitions were < 20%.

Summary of recovery results

Analyte	Matrix	Fortification Level (mg/kg)	Mean Recovery (%)	RSD (%)	n	Overall Mean Recovery (%)	Overall RSD (%)
Deltamethrin	Ion Mass Transition 252.9→172.0 (Quantification)						
	Winter Wheat (ears)	0.01*	103	6.0	5	106	5.4
		0.1	110	2.8	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Winter Wheat (ears)	0.01*	104	2.8	5	105	3.0
		0.1	106	3.3	5		
	Ion Mass Transition 252.9→172.0 (Quantification)						
	Winter Wheat (rest of plants)	0.01*	90	7.5	5	86	9.1
		0.1	83	9.7	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Winter Wheat (rest of plants)	0.01*	87	7.3	5	83	7.9
		0.1	79	5.6	5		
	Ion Mass Transition 252.9→172.0 (Quantification)						
	Winter Wheat (straw)	0.01*	76	6.6	5	78	6.1
		0.1	81	4.4	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Winter Wheat (straw)	0.01*	77	5.8	5	80	6.6
		0.1	83	6.1	5		
	Ion Mass Transition 252.9→172.0 (Quantification)						
	Winter Wheat (grain)	0.01*	106	2.4	5	104	3.7
		0.1	102	3.8	5		
	Ion Mass Transition 250.9→172.0 (Confirmation)						
	Winter Wheat (grain)	0.01*	104	5.8	5	102	5.5
		0.1	101	5.2	5		

*-Limit of quantification, defined by the lowest validated fortification level

Limit of Quantification (LOQ) and Limit of Detection (LOD):

The limit of quantification (LOQ) is the lowest validated fortification level and was thus successfully established at 0.01 mg/kg for both ion mass transitions of Deltamethrin in Winter Wheat matrix. The limit of detection (LOD) for Deltamethrin was set at 0.002 mg/kg for tested matrix, which is < 30% of the LOQ. The limit of detection (LOD) for Deltamethrin was set at 0.003 mg/kg for tested matrix, which is < 30% of the LOQ.

Results obtained for the analysis of Winter Wheat:

Summary of results from residue analysis of Winter Wheat

Crop (matrix)	Field trial sample code – description / Treatment (U-Untreated, B,C-Treated)	Lab. Sample ID	Rep.	Mean Residues of Deltamethrin [mg/kg]
Winter wheat (ears)	B7143 ND1 / U1G / A	17/05/DPL/1/1	3	< LOD
	B7143 ND1 / B1G / A	17/05/DPL/1/2	3	< LOD
	B7143 ND1 / C1G / A	17/05/DPL/1/3	3	<u>0.0639</u>
Winter wheat (rest of plants)	B7143 ND1 / U1S / A	17/05/DPL/1/4	3	< LOD
	B7143 ND1 / B1S / A	17/05/DPL/1/5	3	<u>0.0060 <LOQ</u>
	B7143 ND1 / C1S / A	17/05/DPL/1/6	3	<u>0.242</u>
Winter wheat (ears)	B7143 ND1 / U2G / A	17/05/DPL/1/7	3	< LOD
	B7143 ND1 / B2G / A	17/05/DPL/1/8	3	< LOD
	B7143 ND1 / C2G / A	17/05/DPL/1/9	3	<u>0.0550</u>
Winter wheat (rest of plants)	B7143 ND1 / U2S / A	17/05/DPL/1/10	3	< LOD
	B7143 ND1 / B2S / A	17/05/DPL/1/11	3	<u>0.0337</u>
	B7143 ND1 / C2S / A	17/05/DPL/1/12	3	<u>0.286</u>
Winter wheat (straw)	B7143 ND1 / UHS / A	17/05/DPL/1/13	3	<u>0.0019 < LOQ</u>
	B7143 ND1 / BHS / A	17/05/DPL/1/14	3	<u>0.0177</u>
	B7143 ND1 / CHS / A	17/05/DPL/1/15	3	<u>0.247</u>
Winter wheat (grain)	B7143 ND1 / UHG / A	17/05/DPL/1/16	3	< LOD
	B7143 ND1 / BHG / A	17/05/DPL/1/17	3	< LOD
	B7143 ND1 / CHG / A	17/05/DPL/1/18	3	< LOD
Winter wheat (ears)	B7143 HU1 / U1G / A	17/05/DPL/1/19	3	< LOD
	B7143 HU1 / B1G / A	17/05/DPL/1/20	3	<u>0.0050 <LOQ</u>
	B7143 HU1 / C1G / A	17/05/DPL/1/21	3	<u>0.141</u>
Winter wheat (rest of plants)	B7143 HU1 / U1S / A	17/05/DPL/1/22	3	<u>0.0065 < LOQ</u>
	B7143 HU1 / B1S / A	17/05/DPL/1/23	3	<u>0.0472</u>
	B7143 HU1 / C1S / A	17/05/DPL/1/24	3	<u>0.149</u>

Summary of results from residue analysis of Winter Wheat (cont.)

Crop (matrix)	Field trial sample code – description / Treatment (U-Untreated, B,C-Treated)	Lab. Sample ID	Rep.	Mean Residues of Deltamethrin [mg/kg]
Winter Wheat (ears)	B7143 HU1 / U2G / A	17/05/DPL/1/25	3	< LOD
	B7143 HU1 / B2G / A	17/05/DPL/1/26	3	<u>0.0048 <LOQ</u>
	B7143 HU1 / C2G / A	17/05/DPL/1/27	3	<u>0.184</u>
Winter Wheat (rest of plants)	B7143 HU1 / U2S / A	17/05/DPL/1/28	3	<u>0.0048 < LOQ</u>
	B7143 HU1 / B2S / A	17/05/DPL/1/29	3	<u>0.0413</u>
	B7143 HU1 / C2S / A	17/05/DPL/1/30	3	<u>0.0701</u>
Winter Wheat (straw)	B7143 HU1 / UHS / A	17/05/DPL/1/31	3	< LOD
	B7143 HU1 / BHS / A	17/05/DPL/1/32	3	<u>0.0362</u>
	B7143 HU1 / CHS / A	17/05/DPL/1/33	3	<u>0.124</u>
Winter Wheat (grain)	B7143 HU1 / UHG / A	17/05/DPL/1/34	3	< LOD
	B7143 HU1 / BHG / A	17/05/DPL/1/35	3	< LOD
	B7143 HU1 / CHG / A	17/05/DPL/1/36	3	<u>0.0019 <LOQ</u>
Winter Wheat (ears)	B7143 PL1 / U1G / A	17/05/DPL/1/37	3	< LOD
	B7143 PL1 / B1G / A	17/05/DPL/1/38	3	< LOD
	B7143 PL1 / C1G / A	17/05/DPL/1/39	3	<u>0.0341</u>
Winter Wheat (grain)	B7143 PL1 / U1S / A	17/05/DPL/1/40	3	< LOD
	B7143 PL1 / B1S / A	17/05/DPL/1/41	3	<u>0.0143</u>
	B7143 PL1 / C1S / A	17/05/DPL/1/42	3	<u>0.0574</u>
Winter Wheat (ears)	B7143 PL1 / U2G / A	17/05/DPL/1/43	3	< LOD
	B7143 PL1 / B2G / A	17/05/DPL/1/44	3	< LOD
	B7143 PL1 / C2G / A	17/05/DPL/1/45	3	<u>0.0662</u>
Winter Wheat (rest of plants)	B7143 PL1 / U2S / A	17/05/DPL/1/46	3	< LOD
	B7143 PL1 / B2S / A	17/05/DPL/1/47	3	<u>0.0131</u>
	B7143 PL1 / C2S / A	17/05/DPL/1/48	3	<u>0.0801</u>
Winter Wheat (straw)	B7143 PL1 / UHS / A	17/05/DPL/1/49	3	< LOD
	B7143 PL1 / BHS / A	17/05/DPL/1/50	3	<u>0.0200</u>
	B7143 PL1 / CHS / A	17/05/DPL/1/51	3	<u>0.252</u>
Winter Wheat (grain)	B7143 PL1 / UHG / A	17/05/DPL/1/52	3	< LOD
	B7143 PL1 / BHG / A	17/05/DPL/1/53	3	< LOD
	B7143 PL1 / CHG / A	17/05/DPL/1/54	3	<u>0.0026 <LOQ</u>

Summary of results from residue analysis of Winter Wheat (cont.)

Crop (matrix)	Field trial sample code – description / Treatment (U-Untreated, B,C-Treated)	Lab. Sample ID	Rep.	Mean Residues of Deltamethrin [mg/kg]
Winter Wheat (ears)	B7143 CZ1 / U1G / A	17/05/DPL/1/55	3	< LOD
	B7143 CZ1 / B1G / A	17/05/DPL/1/56	3	< LOD
	B7143 CZ1 / C1G / A	17/05/DPL/1/57	3	<u>0.0392</u>
Winter Wheat (rest of plants)	B7143 CZ1 / U1S / A	17/05/DPL/1/58	3	< LOD
	B7143 CZ1 / B1S / A	17/05/DPL/1/59	3	<u>0.0247</u>
	B7143 CZ1 / C1S / A	17/05/DPL/1/60	3	<u>0.0726</u>
Winter Wheat (ears)	B7143 CZ1 / U2G / A	17/05/DPL/1/61	3	< LOD
	B7143 CZ1 / B2G / A	17/05/DPL/1/62	3	< LOD
	B7143 CZ1 / C2G / A	17/05/DPL/1/63	3	<u>0.0553</u>
Winter Wheat (rest of plants)	B7143 CZ1 / U2S / A	17/05/DPL/1/64	3	< LOD
	B7143 CZ1 / B2S / A	17/05/DPL/1/65	3	<u>0.206</u>
	B7143 CZ1 / C2S / A	17/05/DPL/1/66	3	<u>0.0426</u>
Winter Wheat (straw)	B7143 CZ1 / UHS / A	17/05/DPL/1/67	3	< LOD
	B7143 CZ1 / BHS / A	17/05/DPL/1/68	3	<u>0.0917</u>
	B7143 CZ1 / CHS / A	17/05/DPL/1/69	3	<u>0.101</u>
Winter Wheat (grain)	B7143 CZ1 / UHG / A	17/05/DPL/1/70	3	< LOD
	B7143 CZ1 / BHG / A	17/05/DPL/1/71	3	< LOD
	B7143 CZ1 / CHG / A	17/05/DPL/1/72	3	<u>0.0046 <LOQ</u>

Conclusions

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Deltamethrin, and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for Deltamethrin, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Winter Wheat (rest of plants and straw) and 0.003 mg/kg for Winter Wheat (ears and grain). It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (and SANCO/825/00, rev. 8.1. SANCO/3029/99, rev. 4) and is, applicable as enforcement and data generation method for determination of Deltamethrin in Winter Wheat after application of “DELCAPS 050 CS” AND “DELTAMETHRIN 100 SC”

A 2.2.3.2.2 Study 2

Comments of zRMS:	<p>The report covers only the field part of the study. The relevant analytical part is described in report No ZBBZ-2017/05/DPL/1.</p> <p>The study was conducted under field conditions at 4 sites in Northern Europe (France, Hungary, Poland and Czech Republic).</p> <p>In accordance with the proposed GAP, part of the study regarding the use of DELTAMETHRIN 100 SC was performed and only the results from this part of the study were included in the assessment.</p> <p>The one application of 0.05 L/ha (5g deltamethrin) of DELTAMETHRIN 100 SC was made at BBCH 79, PHI was 30 days.</p> <p>The field part of the study is accepted.</p>
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Reference: KCA 6.3

Report Generation of Field specimens for the determination of Deltamethrin residues in winter wheat following foliar application with DELCAPS 050 CS and DELTAMETHRIN 100 SC under Field conditions in Northern Europe

	in 2017, 2017, Corinne Ertus, B7143
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to generate specimens of winter wheat raw agricultural commodity after one foliar application of the formulated product DELCAPS 50 CS (50 g deltamethrin/L) at the rate of 0.1 L/ha and after one foliar application of the formulated product DELTAMETHRIN 100 SC (100 g deltamethrin/L) at the rate of 0.05 L/ha.

The study consisted of one single phase: the field phase.

The study was conducted under field conditions at sites 4 in Northern Europe. All trials were sampled to monitor the decline of residues after the treatment and at harvest.

In each bridging trial, one plot was treated once with DELCAPS 050 CS at the application rate of 0.1 L F.P./ha (equivalent to 5g/ha as deltamethrin) and another plot was treated once with DELTAMETHRIN 100 SC at the application rate of 0.05 L F.P./ha (equivalent to 5 g/ha as deltamethrin). The application of DELCAPS 050 CS was made at BBCH 59 and 60 days before the harvest (48 days before the harvest trial B7143 ND1*). The application of DELTAMETHRIN 100 SC was made at BBCH 79 and 30 days before harvest.

Samples generated during this study were sent for analysis to the laboratory INSTYTUT OGRODNICTWA.

Deviations:

Deviation No. 170718

*Trial B7143 ND1 plot B (treated with DELCAPS 050 CS):

Because of drought during several weeks, the maturity of the crop was reached earlier than scheduled. Then, the interval between the application and the normal harvest was 48 days instead of 60 +/- 5 days as requested by the study plan. The deviation of 20% from target has no impact on the study as it is within the "25% rule" mentioned in OECD 509. Moreover it is a worst case scenario.

Deviation No. 170828

Trial B7143 CZ1:

The samples were shipped to the wrong laboratory. Mistake in the delivery addressee. The specimens were kept frozen by the first delivered laboratory and shipped under dry ice conditions by the Field Principal Investigator herself to the right laboratory. Dry ice was still present at receipt.

Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of active substance	Spray volume
U	Untreated	--	--	--	--	--
B	DELCAPS 050 CS	B1	BBCH 59 and 60 (± 5) DBH	0.10 L / ha	5 g / ha	200 - 400 L/ha ($\pm 10\%$)
C	DELTAMETHRIN 100 SC	C1	BBCH 79 and 30 (± 3) DBH	0.05 L / ha	5 g /ha	200 - 400 L/ha ($\pm 10\%$)

DBH : Days before harvest

Sampling Details

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, B, C	BBCH 83	Rest of plants Ears	0.5 kg from ≥ 12 plants 1.5 kg
S2	U, B, C	BBCH 85 - 87	Rest of plants Ears	0.5 kg from ≥ 12 plants 1.5 kg
S3	U, B, C	BBCH 89 – 97 (normal harvest)*	Straw Grain	0.5 kg from ≥ 12 plants 1.0 kg

*normal harvest was at 60 (± 5) DAA on plot B and 30 (± 3) DAA on plot C.

DAA: Days after application

Application:

Summary of the actual application(s) data

Trial No.	Plot	Application No.	a.s. rate (g/ha)	Deviation from the intended application rate (%)	Spray volume (L/ha)	Date	Growth stage (BBCH)
B7143 ND1	B	1	5.3	+5.0	210	31/05/2017	59
	C	1	5.4	+7.5	215	15/06/2017	79
B7143 HU1	B	1	5.4	+8.3	325	20/05/2017	59
	C	1	5.3	+5.0	315	20/06/2017	79
B7143 PL1	B	1	5.0	-0.7	298	09/06/2017	59
	C	1	5.0	-0.7	298	06/07/2017	79
B7143 CZ1	B	1	5.5	+9.0	327	05/06/2017	59
	C	1	4.7	-5.7	283	05/07/2017	77-83

Sampling of specimens:

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA		Actual Growth Stage (BBCH)
			Plot B	Plot C	
B7143 ND1	1	21/06/2017	21	6	83
	2	13/07/2017	43	28	87
	3	18/07/2017	48*	33	89
B7143 HU1	1	26/06/2017	37	6	83
	2	28/06/2017	39	8	85-87
	3	19/07/2017	60	29	89-97
B7143 PL1	1	14/07/2017	35	8	83
	2	24/07/2017	45	18	85-87
	3	04/08/2017	56	29	89
B7143 CZ1	1	14/07/2017	39	9	83
	2	24/07/2017	49	19	85-87
	3	01/08/2017	57	27	89

DAA: Days after application

*See Deviation No.170718

A 2.2.3.3 Oilseed rape

zRMS comments:

Comparison of intended and critical EU GAPs for deltamethrin:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (g a.s./ha)	PHI (days)
Rape seed (code 0401060)				
cGAP EU EFSA Journal 2015;13(11):4309	n.a.	4 (14 days)	6.25	45
Intended GAP (major use No 1)	BBCH 10-21	1	4.8	n/a
Intended GAP (major use No 2)	BBCH 30-70	1	4.8	n/a

Summary of the fields reside trials for Deltamethrin in winter oilseed rape (CS type formulation)

Report- No. Location	Commodity/Variety	Date of: 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i./ha	Water l/ha	Kg a.i./hl						

B7022 AN1 Donnelay 57810 Northern France	Oilseed rape / FONZZI	1) 29/08/2016 2) 10/04/2017 To 22/05/2017 3) 10/07/2017	0.0051	304	0.0017	10/04/2017	BBCH 59	Seeds	NDR	90	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
B7022 BW1 Breisach 79206, Germany	Oilseed rape / ARISTOTELES	1) 21/09/2016 2) 28/03/2017 to 22/05/2017 3) 01/07/2017 to 10/07/2017	0.0047	283	0.0017	03/04/2017	BBCH 59	Seeds	NDR	95	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
B7022 HU1 Acs 2941 Hungary	Oilseed rape / HYBRIROCK	1) 02/09/2016 2) 15/04/2017 to 05/05/2017 3) 05/07/2017	0.0052	312	0.0017	10/04/2017	BBCH59	Seeds	NDR	86	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
B7022 UK1 Stratton Audley OX27 9AS United Kingdom	Oilseed rape / TAMARIN	1) 14/04/2017 2) June 2017 to July 2017 3) 15/09/2017	0.0051	304	0.0017	14/06/2017	BBCH 59	Seeds	NDR	93	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

Summary of the fields reside trials for Deltamethrin in winter oilseed rape (SC type formulation)

Report-No. Location	Commodity/Variety	Date of: 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i./ha	Water l/ha	Kg a.i./hl						
C1179/ 99107 Daszyna, Koryta, Lodzkie, Poland/ 2021	Oilseed rape / KUGA	1) 24.08.2020 2) – 3) 22.07.2021	0.0054	432	0.00125	15.06.2021	BBCH 72	Seeds	NDR	37	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1180/ 56125 Rudoltice, Pardubice, Czech Republic/ 2021	Oilseed rape / ATORA	1) 26.08.2020 2) - 3) 31.07.2021	0.0051	307	0.0017	19.06.2021	BBCH 72	Seeds	NDR	42	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1181/ 79206 Breisach am Rhein, Baden- Württemberg, Germany/ 2021	Oilseed rape / ARCHITECT	1) 23.09.2020 2) - 3) 07.07.02021	0.0053	327	0.0012	28.05.2021	BCH 72	Seeds	NDR	40	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

C1182/ 95010 Strykow, Anielin, Lodzkie, Poland/2021	Oilseed rape / Quartz	1) 28.08.2020 2) - 3) 22.07.2021	0.0051	407	0.0013	14.06.2021	BBCH 72	Seeds	NDR	38	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1183/ Vysoké Chvojno, Pardubice, Czech Republic/ 2021	Ilseed rape/ Arabella LG	1) 14.08.2020 2) – 3) 22.07.2021	0.0051	307	0.0017	16.06.2021	BBCH 72	Seeds	NDR	36	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

A 2.2.3.3.1 Study 1

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin in oilseed rape samples taken from the field trials following one application of DELCAPS at the rate of 0.1 L/ha (5 g deltamethrin/ha) at BBCH 59, PHI=90. The study was conducted under field conditions at 4 sites in Northern Europe (FR, GE, HU, UK).</p> <p>Residues were extracted with acetonitrile. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for deltamethrin. The limit of detection (LOD) was 0.003 mg/kg for seed.</p> <p>Residues in all samples of seeds were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>It is not indicated whether trans- and alpha-R-deltamethrin is determined by this method, therefore the results are informative only.</p>
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Reference:	KCA 6.3
Report	DETERMINATION of deltamethrin residues in oilseed rape following foliar application with DelCaps under Field conditions in Northern Europe in 2017, 2018, Agnes Perny, B7022
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin in Oilseed rape raw agricultural commodity after one foliar application of the formulated product DELCAPS 50 g/L deltamethrin), at the rate of 0.1 L/ha.

The study consisted of two phases: the field phase and the analytical phase.
 The study was conducted under field conditions at 4 sites in Northern Europe.
 In each trial one plot was treated once with DELCAPS at the application rate of 0.1 L/ha (5g deltamethrin/ha) The application sampling was made at BBCH 81 and 89, the last sampling being made at 90-95 days after application (DAA).
 In two trials 5 samplings were performed between BBCH 81 and 89, the last sampling being made at 86-93 DAA.

Deltamethrin residues were analysed in samples harvested during the field phase.
 Samples were analysed according to the method validated under ANADIAG study No B7023 entitled "Validation of the analytical method for the analysis of Deltamethrin in Oilseed rape seeds"

Deviations:

Deviation No. B7022 – 170709

Trial B7022 AN1

Only 4 samplings have been made instead of 5 since the growth stage BBCH 89 was reached at 90 DAA. No further sampling was thus necessary. This deviation has no impact on the study: the decline curve includes only 4 dates instead of 5 but the samplings have been carried out as scheduled: between BBCH

81 and 89-97, and at 90 +/- 5 DAA.

Deviation No. B7022 – 170707

Trial B7022 BW1

Only 4 samplings have been made instead of 5, since the growth stage BBCH 89 was reached at 95 DAA. No further sampling was thus necessary.

This deviation has no impact on the study: the decline curve includes only 4 dates instead of 5 but the samplings have been carried out as scheduled: between BBCH 81 and 89-97, and at 90 +/- 5 DAA.

Summarized results:

Trial No.	Deltamethrin residues (mg/kg)					
	Matrix	BBCH 81	BBCH 85	BBCH 87	BBCH 89	86-95 DAA BBCH 89
B7022 AN1	Seeds	NDR	NDR	NDR	-	NDR
B7022 BW1	Seeds	NDR	NDR	NDR	-	NDR
B7022 HU1	Seeds	NDR	NDR	NDR	NDR	NDR
B7022 UK1	Seeds	NDR	NDR	NDR	NDR	NDR

DAA: Days after application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg

LOQ = 0.01 mg/kg

Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	DELCAPS	T1	BBCH 59 and 90 (±5) DBH	0.1 L/ha	5 g/ha	300 L/ha (±10%)

DBH: Days before harvest

Sampling Details

Decline curve trials

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	BBCH 81	Seeds	0.1 kg
S2	U, T	BBCH 85	Seeds	0.1 kg
S3	U, T	BBCH 87	Seeds	0.1 kg
S4	U, T	BBCH 89	Seeds	0.2 kg
S5	U, T	BBCH 89-97 90 (±5) DAA	Seeds	0.5 kg

DAA : Days after application

Application data:

Summary of the actual application(s) data

Trial No.	Plot	Application No.	a.s. rate (g/ha)	Deviation from the intended application rate (%)	Spray volume (L/ha)	Date	Actual Growth stage (BBCH)
B7022 AN1	T	1	5.1	+1.3	304	10/04/2017	59
B7022 BW1	T	1	4.7	-5.7	283	03/04/2017	59
B7022 HU1	T	1	5.2	+4.0	312	10/04/2017	59
B7022 UK1	T	1	5.1	+1.3	304	14/06/2017	59

a.s.: active substance

Sampling summary:

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B7022 AN1	1	25/06/2017	76	81
	2	01/07/2017	82	85
	3	04/07/2017	85	87
	4	See Deviation No.B7022 - 170709		
	5	09/07/2017	90	89
B7022 BW1	1	21/06/2017	79	81
	2	28/06/2017	86	85
	3	03/07/2017	91	87
	4	See Deviation No.B7022 - 170707		
	5	07/07/2017	95	89
B7022 HU1	1	21/06/2017	72	81
	2	27/06/2017	78	85
	3	29/06/2017	80	87
	4	03/07/2017	84	89
	5	05/07/2017	86	89
B7022 UK1	1	30/08/2017	77	81
	2	01/09/2017	79	85
	3	07/09/2017	85	87
	4	12/09/2017	90	89
	5	15/09/2017	93	89

DAA: Days after application

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified , extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B7022 01 09 AA	Oilseedrape seeds	0.010	102.2%	20/09/2017
B7022 04 09 AA	Oilseedrape seeds	0.010	87.3%	27/10/2017
B7022 02 09 AA	Oilseedrape seeds	0.10	90.9%	20/09/2017
B7022 04 07 AA	Oilseedrape seeds	0.10	84.1%	27/10/2017
B7022 04 07 BA	Oilseedrape seeds	0.10	82.4%	27/10/2017

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Seeds	89.4%	7.9%	8.8%	5

A 2.2.3.3.2 Study 2

Comments of zRMS:	The study has not been evaluated. As a general rule, validation of residue methods should be evaluated in dRR Part B Section 5.
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Reference:	KCA 6.3
Report	Validation of the analytical method for the analysis of Deltamethrin in oilseed rape seeds, 2018, Agnes Perny, B7023
Guideline(s):	Regulation (EC) No 1107/2009 SANCO/3029/99 rev. 4 SANCO/825/00 rev. 8.1 ENV/JM/MONO(2007)17
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Methods:

The method under discussion describes the determination of residues of deltamethrin in oilseed rape seeds. The method was validated at 0.01 mg/kg in oilseed rape seeds. The following points were examined during the study.

Linearity of the analytical method:

The linearity of the method was studied between 0.8 ng/ml and 30ng/ml of deltamethrin in matrix matched calibration solutions (corresponding to 0.003 to 0.12 in mg/kg). The linear corelation coefficients were typically >0.990, showing a good linearity.

Sensitivity:

The limit of quantification (LOQ) is the lowest validated level where a mean recovery within the range 70-110% with RSD less than 20% could be obtained. The LOQ was set at 0.01 mg/kg in oilseed rape seeds.

Recovery results

Analyte	Matrix	Fortification level (mg/kg)	Mean Percentage recovery (%)	Standard deviation (SD) (%)	Relative standard deviation (RSD) (%)	Number of fortified samples (n)
Deltamethrin	oilseed rape seeds	LOQ	104.7%	2.3%	2.2%	5
		10 x LOQ	92.6%	1.8%	1.9%	5
		All levels	98.7%	6.7%	6.8%	10

Accuracy:

The accuracy of the method was assessed on the basis of the determined recovery rates.

	Deltamethrin	
Matrix	oilseed rape seeds	
Fortification level (mg/kg)	0.01	0.10
Single recovery rates	101.3 to 107.7%	91.3 to 95.2%
Mean recoveries per fortification level	104.7%	92.6%

The accuracy of the method fulfils the requirements for residue analytical methods which demand that the mean recovery per fortification level should be in range 70-110%

Precision and repeatability:

Repeatability test (5 recoveries at each fortification level) were performed at the LOQ level and at 10 x LOQ for oilseed rape seeds.

	Deltamethrin	
Matrix	oilseed rape seeds	
Fortification level (mg/kg)	0.01	0.10
RSD for each fortification level	2.2%	1.9%

RSD determined were less than 20%, the method therefor fulfils the requirements for residue analytical methods.

Specificity:

The method is able to determine deltamethrin in oilseed rape seeds. This was checked by analysing control and spiked specimens to verify the absence of interfering peaks. No interfering peaks were present at >30% of the LOQ. The analyses were carried out by LC-MS/MS, monitoring two transitions. The method was considered highly specific, thus the use of an alternative method was not necessary.

Confirmatory Method:

Repeatability test (5 recoveries) were performed at the LOQ level for oilseed rape seeds for the qualification transition.

Summary of recoveries

Analyte	Matrix	Fortification level (mg/kg)	Mean Percentage recovery (%)	Standard deviation (SD) (%)	Relative standard deviation (RSD) (%)	Number of fortified samples (n)
Deltamethrin	oilseed rape seeds	0.01	103.5%	0.9%	0.9%	5

Recoveries and precision data for the qualifier transition comply with the requirements of SANCO/3029/99 rev.4 as the mean recovery at the LOQ level is within the range 70-110% and RSD is less than 20%.

A 2.2.3.3.3 Study 3

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in oilseed rape samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 72, PHI=37 (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Poland.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 1 day for seeds.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples of seeds were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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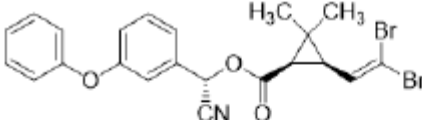
Reference:	KCA 6.3
Report	Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2021, E. Thomas-Delille, Study code: C1179
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Oilseed Rape raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled at harvest. One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 72. One plot remained untreated. Sampling was performed at maturity of the crop at BBCH 89 in both plots. Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.”

Test item

Trade or Code Name	CHR/I/DEL 100 SC
Active substance (a.s.)	Deltamethrin
Formulation type	SC
CAS Number	[52918-63-5]
Nominal content of a.s.	100 g/L
C.A. name of a.s.	(S)-cyano(3-phenoxyphenyl)methyl (1R,3R)-3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate
Structural formula of a.s.	
Batch number*	INNO20
Actual content*	9.46 %
Expiry date*	31/07/2023
Storage conditions	5 - 30°C in the dark

* Certificate(s) of analysis in appendix I.

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 72	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Residue at harvest trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	Maturity BBCH 89	Seeds	0.5 kg

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for deltamethrin and its alpha-R-isomer and trans-isomer in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)	
		Maturity, BBCH 89 and 37 DAA	
		Deltamethrin	Sum of Deltamethrin Trans-deltamethrin and alpha-R-isomer of deltamethrin
C1179 PL1	Seeds	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1179 PL1 / UH / A	22/07/2021	37	89	Seeds	> 12 / 12	0.702	01h50
C1179 PL1 / UH / R	22/07/2021	37	89	Seeds	> 12 / 12	0.708	01h50
C1179 PL1 / TH / A	22/07/2021	37	89	Seeds	> 12 / 12	0.610	01h15
C1179 PL1 / TH / R	22/07/2021	37	89	Seeds	> 12 / 12	0.600	01h15

*..... / A: Specimen for analysis

/ R: Spare specimen

DAA: Days After Application

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1179 PL1 / UH / A	21	Frozen ⁽²⁾	12/08/2021	13/08/2021	1	Frozen ⁽²⁾
C1179 PL1 / TH / A	21	Frozen ⁽²⁾	12/08/2021	13/08/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

2.2.8 Fortification procedure

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent).

During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S491 11	Seeds	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S491 AA	Seeds	0.01	91.3%	88.1%	88.5%	06/09/2021
S491 BA	Seeds	0.01	92.7%	83.8%	95.7%	06/09/2021
S491 CA	Seeds	0.10	96.5%	91.3%	96.4%	06/09/2021

Summary of fortifications in seeds

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	93.5%	2.7%	2.9%	3
Trans-Deltamethrin	87.7%	3.8%	4.3%	3
Alpha-R-isomer of deltamethrin	93.5%	4.4%	4.7%	3

A 2.2.3.3.4 Study 4

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in oilseed rape samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 72, PHI=42 (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Czech Republic.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 1 day for seeds.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples of seeds were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:

KCA 6.3

Report

Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100

SC under Field Conditions in Northern Europe in 2021, 2021, E. Thomas-deille, Study code: C1180

Guideline(s): Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Oilseed Rape raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 72.

One plot remained untreated.

Sampling was performed at maturity of the crop at BBCH 89 in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for Deltamethrin, Trans-deltamethrin and alpha-R-isomer of Deltamethrin in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)	
		Maturity, BBCH 89 and 42 DAA	
		Deltamethrin	Sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin
C1180 CZ1	Seeds	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

The following pattern was designed for the treatments and the samplings:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 72	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Residue at harvest trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	Maturity BBCH 89	Seeds	0.5 kg

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1180 CZ1 / UH / A	31/07/2021	42	89	Seeds	n.r. / > 12	0.530	02h05
C1180 CZ1 / UH / R	31/07/2021	42	89	Seeds	n.r. / > 12	0.546	02h05
C1180 CZ1 / TH / A	31/07/2021	42	89	Seeds	n.r. / > 12	0.562	01h25
C1180 CZ1 / TH / R	31/07/2021	42	89	Seeds	n.r. / > 12	0.542	01h25

*..... / A: Specimen for analysis

/ R: Spare specimen

DAA: Days After Application

n.r. not recorded

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1180 CZ1 / UH / A	12	Frozen ⁽²⁾	12/08/2021	13/08/2021	1	Frozen ⁽²⁾
C1180 CZ1 / TH / A	12	Frozen ⁽²⁾	12/08/2021	13/08/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S491 11	Seeds	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S491 AA	Seeds	0.01	91.3%	88.1%	88.5%	06/09/2021
S491 BA	Seeds	0.01	92.7%	83.8%	95.7%	06/09/2021
S491 CA	Seeds	0.10	96.5%	91.3%	96.4%	06/09/2021

Summary of fortifications in seeds

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	93.5%	2.7%	2.9%	3
Trans-Deltamethrin	87.7%	3.8%	4.3%	3
Alpha-R-isomer of deltamethrin	93.5%	4.4%	4.7%	3

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1180 CZ1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin And Alpha-R-isomer of deltamethrin residues found (mg/kg)
C1180 01 01	C1180 CZ1 / UH / A	-	Seeds	-	NDR	NDR
C1180 01 02	C1180 CZ1 / TH / A	CHR/I/DEL 100 SC	Seeds	42	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.3.5 Study 5

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in oilseed rape samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 72, PHI=40 (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Germany.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p>
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	<p>After extraction, samples were stored below -18°C and analysed after maximum 1 day for seeds.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples of seeds were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference: KCA 6.3

Report Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2021, E. Thomas-Delille, Study code: B1181

Guideline(s): Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Oilseed Rape raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 72.

One plot remained untreated.

Sampling was performed at maturity of the crop at BBCH 89 in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for Deltamethrin, Trans-Deltamethrin and alpha-R-isomer of Deltamethrin in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)	
		Maturity, BBCH 89 and 40 DAA	
		Deltamethrin	Sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin
C1181 BW1	Seeds	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 72	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Residue at harvest trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	Maturity BBCH 89	Seeds	0.5 kg

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1181 BW1 / UH / A	07/07/2021	40	89	Seeds	> 100 / > 30	0.56	03h00
C1181 BW1 / UH / R	07/07/2021	40	89	Seeds	> 100 / > 30	0.57	03h00
C1181 BW1 / TH / A	07/07/2021	40	89	Seeds	> 100 / > 30	0.56	02h25
C1181 BW1 / TH / R	07/07/2021	40	89	Seeds	> 100 / > 30	0.55	02h25

*..... / A: Specimen for analysis

/ R: Spare specimen

DAA: Days After Application

Note: on 06/07/2021, the farmer performed a windrow and the sampling was done 07/07/2021.

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1181 BW1 / UH / A	8	Frozen ⁽²⁾	15/07/2021	15/07/2021	< 1	Frozen ⁽²⁾
C1181 BW1 / TH / A	8	Frozen ⁽²⁾	15/07/2021	15/07/2021	< 1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S491 11	Seeds	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S491 AA	Seeds	0.01	91.3%	88.1%	88.5%	06/09/2021
S491 BA	Seeds	0.01	92.7%	83.8%	95.7%	06/09/2021
S491 CA	Seeds	0.10	96.5%	91.3%	96.4%	06/09/2021

Summary of fortifications in seeds

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	93.5%	2.7%	2.9%	3
Trans-Deltamethrin	87.7%	3.8%	4.3%	3
Alpha-R-isomer of deltamethrin	93.5%	4.4%	4.7%	3

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1181 BW1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin And Alpha-R-isomer of deltamethrin residues found (mg/kg)
C1181 01 01	C1181 BW1 / UH / A	-	Seeds	-	NDR	NDR
C1181 01 02	C1181 BW1 / TH / A	CHR/I/DEL 100 SC	Seeds	40	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.3.6 Study 6

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in oilseed rape samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 72, PHI=40 (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Poland.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 1 day for seeds.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples of seeds were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2021, E. Thomas-Delille, Study code: C1182
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Oilseed Rape raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 72.

One plot remained untreated.

Samplings were performed just before application in the untreated plot, just after application in the treated plot, then 14 days after application and at BBCH 89 (at maturity of the crop) in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for Deltamethrin, Trans-Deltamethrin and alpha-R-isomer of Deltamethrin in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)					
		Deltamethrin			Sum of Deltamethrin, Trans-deltamethrin And alpha-R-isomer of deltamethrin		
		0 DAA	14 DAA	Maturity, BBCH 89 and 38 DAA	0 DAA	14 DAA	Maturity, BBCH 89 and 38 DAA
C1182 PL1	Pods	0.04	0.03	-	0.04	0.03	-
	Rest of plants without pods	0.03	0.03	-	0.03	0.03	-
	Seeds	-	-	NDR	-	-	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR//DEL 100 SC	T1	BBCH 72	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR//DEL 100 SC.

1.1.1.2 Sampling Details

Decline curve trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U	0 DBA	Pods	0.5 kg
			Rest of plants without pods	1 kg Min. 12 plants
	T	0 DAA	Pods	0.5 kg
			Rest of plants without pods	1 kg Min. 12 plants
S2	U, T	14 (±1) DAA	Pods	0.5 kg
			Rest of plants without pods	1 kg Min. 12 plants
S3	U, T	Maturity BBCH 89	Seeds	0.5 kg

DBA : Days before application

DAA : Days after application

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1182 PL1 / U0p / A	14/06/2021	0 DBA	72	Pods	> 12 / 12	0.908	02h45
C1182 PL1 / U0p / R	14/06/2021	0 DBA	72	Pods	> 12 / 12	0.926	02h45
C1182 PL1 / U0r / A	14/06/2021	0 DBA	72	Rest of plants without pods	12 / 12	1.346	02h45
C1182 PL1 / U0r / R	14/06/2021	0 DBA	72	Rest of plants without pods	12 / 12	1.402	02h45
C1182 PL1 / T0p / A	14/06/2021	0	72	Pods	> 12 / 12	1.014	00h45
C1182 PL1 / T0p / R	14/06/2021	0	72	Pods	> 12 / 12	1.042	00h45
C1182 PL1 / T0r / A	14/06/2021	0	72	Rest of plants without pods	12 / 12	1.456	00h45
C1182 PL1 / T0r / R	14/06/2021	0	72	Rest of plants without pods	12 / 12	1.594	00h45
C1182 PL1 / U14p / A	28/06/2021	14	78 - 79	Pods	> 12 / 12	1.004	01h40
C1182 PL1 / U14p / R	28/06/2021	14	78 - 79	Pods	> 12 / 12	1.022	01h40
C1182 PL1 / U14r / A	28/06/2021	14	78 - 79	Rest of plants without pods	12 / 12	1.614	01h40
C1182 PL1 / U14r / R	28/06/2021	14	78 - 79	Rest of plants without pods	12 / 12	1.610	01h40
C1182 PL1 / T14p / A	28/06/2021	14	78 - 79	Pods	> 12 / 12	1.154	00h50
C1182 PL1 / T14p / R	28/06/2021	14	78 - 79	Pods	> 12 / 12	1.070	00h50
C1182 PL1 / T14r / A	28/06/2021	14	78 - 79	Rest of plants without pods	12 / 12	1.370	00h50
C1182 PL1 / T14r / R	28/06/2021	14	78 - 79	Rest of plants without pods	12 / 12	1.338	00h50
C1182 PL1 / UH / A	22/07/2021	38	89	Seeds	> 12 / 12	0.712	04h15
C1182 PL1 / UH / R	22/07/2021	38	89	Seeds	> 12 / 12	0.706	04h15
C1182 PL1 / TH / A	22/07/2021	38	89	Seeds	> 12 / 12	0.784	03h40
C1182 PL1 / TH / R	22/07/2021	38	89	Seeds	> 12 / 12	0.782	03h40

*..... / A: Specimen for analysis

/ R: Spare specimen

DBA: Days Before Application

DAA: Days After Application

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1182 PL1 / U0p / A	38	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / U0r / A	38	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / T0p / A	38	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / T0r / A	38	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / U14p / A	24	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / U14r / A	24	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / T14p / A	24	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / T14r / A	24	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1182 PL1 / UH / A	21	Frozen ⁽²⁾	12/08/2021	13/08/2021	1	Frozen ⁽²⁾
C1182 PL1 / TH / A	21	Frozen ⁽²⁾	12/08/2021	13/08/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S491 11	Seeds	NDR	NDR	NDR
S489 11	Pods	NDR	NDR	NDR
S490 11	Rest of plants without pods	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S491 AA	Seeds	0.01	91.3%	88.1%	88.5%	06/09/2021
S491 BA	Seeds	0.01	92.7%	83.8%	95.7%	06/09/2021
S491 CA	Seeds	0.10	96.5%	91.3%	96.4%	06/09/2021
S489 AA	Pods	0.01	73.3%	68.5%	78.6%	10/09/2021
S489 BA	Pods	0.01	70.8%	63.2%	75.5%	10/09/2021
S489 CA	Pods	0.10	76.1%	70.3%	80.4%	10/09/2021
S490 AA	Rest of plants without pods	0.01	76.9%	88.4%	90.4%	13/09/2021
S490 BA	Rest of plants without pods	0.10	73.7%	71.6%	74.2%	13/09/2021
S490 CA d10	Rest of plants without pods	1.0	83.5%	81.9%	83.4%	13/09/2021

Summary of fortifications in seeds

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	93.5%	2.7%	2.9%	3
Trans-Deltamethrin	87.7%	3.8%	4.3%	3
Alpha-R-isomer of deltamethrin	93.5%	4.4%	4.7%	3

Summary of fortifications in pods

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	73.4%	2.7%	3.6%	3
Trans-Deltamethrin	67.3%	3.7%	5.5%	3
Alpha-R-isomer of deltamethrin	78.2%	2.5%	3.2%	3

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1182 PL1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin residues found (mg/kg)
C1182 01 01	C1182 PL1 / U0p / A	-	Pods	-	NDR	NDR
C1182 01 02	C1182 PL1 / U0r / A	-	Rest of plants without pods	-	NDR	NDR
C1182 01 03	C1182 PL1 / T0p / A	CHR//DEL 100 SC	Pods	0	0.04	0.04
C1182 01 04	C1182 PL1 / T0r / A	CHR//DEL 100 SC	Rest of plants without pods	0	0.03	0.03
C1182 01 05	C1182 PL1 / U14p / A	-	Pods	-	NDR	NDR
C1182 01 06	C1182 PL1 / U14r / A	-	Rest of plants without pods	-	NDR	NDR
C1182 01 07	C1182 PL1 / T14p / A	CHR//DEL 100 SC	Pods	14	0.03	0.03
C1182 01 08	C1182 PL1 / T14r / A	CHR//DEL 100 SC	Rest of plants without pods	14	0.03	0.03
C1182 01 09	C1182 PL1 / UH / A	-	Seeds	-	NDR	NDR
C1182 01 10	C1182 PL1 / TH / A	CHR//DEL 100 SC	Seeds	38	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.3.7 Study 7

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in oilseed rape samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 72, PHI=36 (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Czech Republic.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 1 day for seeds.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples of seeds were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Oilseed Rape Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2021, E. Thomas-Delille C1183
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Oilseed Rape raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 72.

One plot remained untreated.

Samplings were performed just before application in the untreated plot, just after application in the treated plot, then 15 days after application and at BBCH 89 (at maturity of the crop) in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for Deltamethrin, Trans-Deltamethrin and alpha-R isomer of deltamethrin in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)					
		Deltamethrin			Sum of Deltamethrin, Trans-deltamethrin And alpha-R-isomer of deltamethrin		
		0 DAA	15 DAA	Maturity, BBCH 89 and 36 DAA	0 DAA	15 DAA	Maturity, BBCH 89 and 36 DAA
C1183 CZ1	Pods	0.03	0.02	-	0.03	0.02	-
	Rest of plants without pods	0.03	0.01	-	0.03	0.01	-
	Seeds	-	-	NDR	-	-	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR//DEL 100 SC	T1	BBCH 72	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR//DEL 100 SC.

1.1.1.2 Sampling Details

Decline curve trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U	0 DBA	Pods	0.5 kg
			Rest of plants without pods	1 kg Min. 12 plants
	T	0 DAA	Pods	0.5 kg
			Rest of plants without pods	1 kg Min. 12 plants
S2	U, T	14 (±1) DAA	Pods	0.5 kg
			Rest of plants without pods	1 kg Min. 12 plants
S3	U, T	Maturity BBCH 89	Seeds	0.5 kg

DBA : Days before application
 DAA : Days after application

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1183 CZ1 / U0p / A	16/06/2021	0 DBA	72	Pods	n.r. / 12	0.550	02h50
C1183 CZ1 / U0p / R	16/06/2021	0 DBA	72	Pods	n.r. / 12	0.594	02h50
C1183 CZ1 / U0r / A	16/06/2021	0 DBA	72	Rest of plants without pods	14 / 12	1.024	02h40
C1183 CZ1 / U0r / R	16/06/2021	0 DBA	72	Rest of plants without pods	14 / 12	1.020	02h40
C1183 CZ1 / T0p / A	16/06/2021	0	72	Pods	n.r. / 12	0.556	01h30
C1183 CZ1 / T0p / R	16/06/2021	0	72	Pods	n.r. / 12	0.564	01h30
C1183 CZ1 / T0r / A	16/06/2021	0	72	Rest of plants without pods	16 / 12	1.048	01h20
C1183 CZ1 / T0r / R	16/06/2021	0	72	Rest of plants without pods	15 / 12	1.016	01h20
C1183 CZ1 / U14p / A	01/07/2021	15	79	Pods	n.r. / 12	0.556	02h25
C1183 CZ1 / U14p / R	01/07/2021	15	79	Pods	n.r. / 12	0.574	02h25
C1183 CZ1 / U14r / A	01/07/2021	15	79	Rest of plants without pods	30 / > 12	1.074	02h25
C1183 CZ1 / U14r / R	01/07/2021	15	79	Rest of plants without pods	30 / > 12	1.082	02h25
C1183 CZ1 / T14p / A	01/07/2021	15	79	Pods	n.r. / > 12	0.586	01h55
C1183 CZ1 / T14p / R	01/07/2021	15	79	Pods	n.r. / > 12	0.582	01h55
C1183 CZ1 / T14r / A	01/07/2021	15	79	Rest of plants without pods	32 / > 12	1.090	01h55
C1183 CZ1 / T14r / R	01/07/2021	15	79	Rest of plants without pods	32 / > 12	1.026	01h55
C1183 CZ1 / UH / A	22/07/2021	36	89	Seeds	n.r. / > 12	0.502	01h20
C1183 CZ1 / UH / R	22/07/2021	36	89	Seeds	n.r. / > 12	0.506	01h20
C1183 CZ1 / TH / A	22/07/2021	36	89	Seeds	n.r. / > 12	0.508	01h19
C1183 CZ1 / TH / R	22/07/2021	36	89	Seeds	n.r. / > 12	0.506	01h20

*..... / A: Specimen for analysis
 / R: Spare specimen
 DBA: Days Before Application
 DAA: Days After Application
 n.r. not recorded

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1183 CZ1 / U0p / A	36	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / U0r / A	36	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / T0p / A	36	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / T0r / A	36	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / U14p / A	21	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / U14r / A	21	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / T14p / A	21	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / T14r / A	21	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / UH / A	< 1	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾
C1183 CZ1 / TH / A	< 1	Frozen ⁽²⁾	22/07/2021	23/07/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S491 11	Seeds	NDR	NDR	NDR
S489 11	Pods	NDR	NDR	NDR
S490 11	Rest of plants without pods	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S491 AA	Seeds	0.01	91.3%	88.1%	88.5%	06/09/2021
S491 BA	Seeds	0.01	92.7%	83.8%	95.7%	06/09/2021
S491 CA	Seeds	0.10	96.5%	91.3%	96.4%	06/09/2021
S489 AA	Pods	0.01	73.3%	68.5%	78.6%	10/09/2021
S489 BA	Pods	0.01	70.8%	63.2%	75.5%	10/09/2021
S489 CA	Pods	0.10	76.1%	70.3%	80.4%	10/09/2021
S490 AA	Rest of plants without pods	0.01	76.9%	88.4%	90.4%	13/09/2021
S490 BA	Rest of plants without pods	0.10	73.7%	71.6%	74.2%	13/09/2021
S490 CA d10	Rest of plants without pods	1.0	83.5%	81.9%	83.4%	13/09/2021

Summary of fortifications in seeds

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	93.5%	2.7%	2.9%	3
Trans-Deltamethrin	87.7%	3.8%	4.3%	3
Alpha-R-isomer of deltamethrin	93.5%	4.4%	4.7%	3

Summary of fortifications in pods

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	73.4%	2.7%	3.6%	3
Trans-Deltamethrin	67.3%	3.7%	5.5%	3
Alpha-R-isomer of deltamethrin	78.2%	2.5%	3.2%	3

Summary of fortifications in rest of plants without pods

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	78.0%	5.0%	6.4%	3
Trans-Deltamethrin	80.6%	8.5%	10.5%	3
Alpha-R-isomer of deltamethrin	82.7%	8.1%	9.8%	3

Summary of fortifications in all matrices

Analyte	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Deltamethrin	81.6%	9.6%	11.8%	3
Trans-Deltamethrin	78.6%	10.3%	13.1%	3
Alpha-R-isomer of deltamethrin	84.8%	8.3%	9.8%	3

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1183 CZ1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin residues found (mg/kg)
C1183 01 01	C1183 CZ1 / U0p / A	-	Pods	-	NDR	NDR
C1183 01 02	C1183 CZ1 / U0r / A	-	Rest of plants without pods	-	NDR	NDR
C1183 01 03	C1183 CZ1 / T0p / A	CHR//DEL 100 SC	Pods	0	0.03	0.03
C1183 01 04	C1183 CZ1 / T0r / A	CHR//DEL 100 SC	Rest of plants without pods	0	0.03	0.03
C1183 01 05	C1183 CZ1 / U14p / A	-	Pods	-	NDR	NDR
C1183 01 06	C1183 CZ1 / U14r / A	-	Rest of plants without pods	-	NDR	NDR
C1183 01 07	C1183 CZ1 / T14p / A	CHR//DEL 100 SC	Pods	15	0.02	0.02
C1183 01 08	C1183 CZ1 / T14r / A	CHR//DEL 100 SC	Rest of plants without pods	15	0.01	0.01
C1183 01 09	C1183 CZ1 / UH / A	-	Seeds	-	NDR	NDR
C1183 01 10	C1183 CZ1 / TH / A	CHR//DEL 100 SC	Seeds	36	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.4 Sugarbeet

zRMS comments:

Comparison of intended and critical EU GAPs for deltamethrin:

Type of GAP	Growth stage at last appl.	Number of applications (interval between appl.)	App. rate per treatment (g a.s./ha)	PHI (days)
Sugar beet (code 900010)				
cGAP EU EFSA Journal 2015;13(11):4309	n.a.	3	10	3
Intended GAP (major use No 5)	BBCH 12-19	1	4.8	n/a

Summary of the fields reside trials for Deltamethrin in sugarbeet (SC type formulation)

Report-No. Location	Commodity/Variety	Date of: 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatment and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			Kg a.i./ha	Water l/ha	Kg a.i./hl						

C1147/ 59189 Steenbecque, Hauts-de- France, France/ 2021	Sugar beet/ Caledia	1) 02.02.2021 2) – 3) 05.10.2021	0.0051	307	0.0017	16.06.2021	BBCH 37	Root and leaves with tops	NDR	111	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1148/ 99122 Morakow, Lodzkie, Poland/ 2021	Sugar beet/ Wojownik	1) 10.04.2021 2) – 3) 21.09.2021	0.0054	435	0.0012	16.06.2021	BBCH 37	Roots and leaves with tops	NDR	97	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1149/ 56601 Tisova, Pardubice, Czech Republic/ 2021	Sugarbeet Conviso	1) 20.03.2021 2) – 3) 11.10.2021	0.0048	287	0.0017	02.07.2021	BBCH 37	Root and leaves with tops	NDR for roots 0.01 for leaves with tops	101	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1150/ 67160 Seebach, Grand Est, France/ 2021	Sugarbeet/ Jellara kws	1) 01.04.2021 2) – 3) 27.09.2021	0.0049	393	0.0012	16.06.2021	BBCH 37	Root and leaves with tops	NDR	103	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg
C1151/ 79415 Bad Bellingen, Baden- Württemberg,	Sugarbeet/ Lisanna	1) 23.03.2021 2) – 3) 28.10.2021	0.0048	383	0.0013	14.06.2021	BBCH 37	Roots and leaves with tops	NDR	136	LOQ = 0.01 mg/kg LOD = 0.003

Germany/ 2021											mg/kg
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A 2.2.3.4.1 Study 1

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in sugar beet samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 37, (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Northern France.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 5 days for leaves with tops and 3 days for roots.</p> <p>Results of storage stability of extracts in ANADIAG validation study No. C1145 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer metabolites in Sugar beet.” showed a good stability of deltamethrin, trans-deltamethrin and alpha-R-isomer of deltamethrin residues in sugar beet leaves with top and sugar beet roots extracts for at least 15 days and 17 days respectively of frozen storage.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples (roots and leaves with tops) were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:

KCA 6.3

Report

Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2022, E. Thomas-Delille, Study code: C1147

Guideline(s):

Regulation (EC) No 1107/2009

Deviations:

No

GLP:

Yes

Acceptability:

Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Sugar Beet raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase.

The study was conducted under field conditions at one site in Northern Europe. The trial was sampled at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 37.

One plot remained untreated.

Sampling was performed at maturity of the crop at BBCH 49 in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for deltamethrin and its alpha-R-isomer and trans-isomer in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)	
		Maturity, BBCH 49 (111 DAA)	
		Deltamethrin	Sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin
C1147 ND1	Leaves with tops	NDR	NDR
	Roots	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 37	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Residue at harvest trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	Maturity BBCH 49	Leaves with tops	From min. 12 plants
			Roots	

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units** / zones	Specimen size (kg)	Sampling to freezing time
C1147 ND1 / UHL / A	05/10/2021	111	49	Leaves with tops	> 12 / > 12	2.954	02h45
C1147 ND1 / UHL / R	05/10/2021	111	49	Leaves with tops	> 12 / > 12	2.350	02h45
C1147 ND1 / UHR / A	05/10/2021	111	49	Roots	> 12 / > 12	5.950	01h45
C1147 ND1 / UHR / R	05/10/2021	111	49	Roots	> 12 / > 12	5.304	01h45
C1147 ND1 / THL / A	05/10/2021	111	49	Leaves with tops	> 12 / > 12	2.664	01h15
C1147 ND1 / THL / R	05/10/2021	111	49	Leaves with tops	> 12 / > 12	1.778	01h15
C1147 ND1 / THR / A	05/10/2021	111	49	Roots	> 12 / > 12	5.378	00h15
C1147 ND1 / THR / R	05/10/2021	111	49	Roots	> 12 / > 12	4.692	00h15

*..... / A: Specimen for analysis

/ R: Spare specimen

DAA: Days After Application

**subsampling: leaves with tops and roots were quartered: 2 opposite quarters were sampled for analytical samples and 2 opposite quarters for retain samples.

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1147 ND1 / UHL / A	9	Frozen ⁽²⁾	14/10/2021	15/10/2021	1	Frozen ⁽²⁾
C1147 ND1 / UHR / A	9	Frozen ⁽²⁾	14/10/2021	15/10/2021	1	Frozen ⁽²⁾
C1147 ND1 / THL / A	9	Frozen ⁽²⁾	14/10/2021	15/10/2021	1	Frozen ⁽²⁾
C1147 ND1 / THR / A	9	Frozen ⁽²⁾	14/10/2021	15/10/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S512 02 11	Leaves with tops	NDR	NDR	NDR
S513 02 11	Roots	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S513 02 AA	Roots	0.01	65.0%	104.0%	70.9%	18/11/2021
S513 02 BA	Roots	0.01	65.6%	113.2%	76.4%	18/11/2021
S513 02 CA	Roots	0.1	74.0%	80.3%	76.6%	18/11/2021
S512 02 AA	Leaves with tops	0.01	72.2%	72.3%	73.3%	16/11/2021
S512 02 BA	Leaves with tops	0.01	88.9%	91.5%	99.9%	16/11/2021
S512 02 CA	Leaves with tops	0.10	70.3%	72.0%	70.6%	16/11/2021

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1147 ND1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin And Alpha-R-isomer of deltamethrin residues found (mg/kg)
C1147 01 01	C1147 ND1 / UHL / A	-	Leaves with tops	-	NDR	NDR
C1147 01 02	C1147 ND1 / UHR / A	-	Roots	-	NDR	NDR
C1147 01 03	C1147 ND1 / THL / A	CHR//DEL 100 SC	Leaves with tops	111	NDR	NDR
C1147 01 04	C1147 ND1 / THR / A	CHR//DEL 100 SC	Roots	111	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.4.2 Study 2

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in sugar beet samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 37, (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Poland.</p>
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	<p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 5 days for leaves with tops and 3 days for roots.</p> <p>Results of storage stability of extracts in ANADIAG validation study No. C1145 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer metabolites in Sugar beet.” showed a good stability of deltamethrin, trans-deltamethrin and alpha-R-isomer of deltamethrin residues in sugar beet leaves with top and sugar beet roots extracts for at least 15 days and 17 days respectively of frozen storage.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples (roots and leaves with tops) were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference: KCA 6.3

Report Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2022, E. Thomas-deille, Study code: C1148

Guideline(s): Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Sugar Beet raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 37.

One plot remained untreated.

Sampling was performed at maturity of the crop at BBCH 49 in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for deltamethrin and its alpha-R-isomer and trans-isomer in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)	
		Maturity, BBCH 49 (97 DAA)	
		Deltamethrin	Sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin
C1148 PL1	Leaves with tops	NDR	NDR
	Roots	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 37	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Residue at harvest trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	Maturity BBCH 49	Leaves with tops	From min. 12 plants
			Roots	

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units** / zones	Specimen size (kg)	Sampling to freezing time
C1148 PL1 / UHL / A	21/09/2021	97	49	Leaves with tops	12 / 12	3.530	02h30
C1148 PL1 / UHL / R	21/09/2021	97	49	Leaves with tops	12 / 12	3.516	02h30
C1148 PL1 / UHR / A	21/09/2021	97	49	Roots	12 / 12	6.674	02h30
C1148 PL1 / UHR / R	21/09/2021	97	49	Roots	12 / 12	6.320	02h30
C1148 PL1 / THL / A	21/09/2021	97	49	Leaves with tops	12 / 12	2.916	02h00
C1148 PL1 / THL / R	21/09/2021	97	49	Leaves with tops	12 / 12	3.024	02h00
C1148 PL1 / THR / A	21/09/2021	97	49	Roots	12 / 12	6.302	02h00
C1148 PL1 / THR / R	21/09/2021	97	49	Roots	12 / 12	6.122	02h00

*..... / A: Specimen for analysis

/ R: Spare specimen

DAA: Days After Application

**subsampling: leaves with tops and roots were quartered: 2 opposite quarters were sampled for analytical samples and 2 opposite quarters for retain samples.

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1148 PL1 / UHL / A	30	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾
C1148 PL1 / UHR / A	30	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾
C1148 PL1 / THL / A	30	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾
C1148 PL1 / THR / A	30	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S512 02 11	Leaves with tops	NDR	NDR	NDR
S513 02 11	Roots	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S513 02 AA	Roots	0.01	65.0%	104.0%	70.9%	18/11/2021
S513 02 BA	Roots	0.01	65.6%	113.2%	76.4%	18/11/2021
S513 02 CA	Roots	0.10	74.0%	80.3%	76.6%	18/11/2021
S512 02 AA	Leaves with tops	0.01	72.2%	72.3%	73.3%	16/11/2021
S512 02 BA	Leaves with tops	0.01	88.9%	91.5%	99.9%	16/11/2021
S512 02 CA	Leaves with tops	0.10	70.3%	72.0%	70.6%	16/11/2021

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1148 PL1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin And alpha-R-isomer of deltamethrin residues found (mg/kg)
C1148 01 01	C1148 PL1 / UHL / A	-	Leaves with tops	-	NDR	NDR
C1148 01 02	C1148 PL1 / UHR / A	-	Roots	-	NDR	NDR
C1148 01 03	C1148 PL1 / THL / A	CHR/I/DEL 100 SC	Leaves with tops	97	NDR	NDR
C1148 01 04	C1148 PL1 / THR / A	CHR/I/DEL 100 SC	Roots	97	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.4.3 Study 3

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in sugar beet samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 37, (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Czech Republic.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 5</p>
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	<p>days for leaves with tops and 3 days for roots.</p> <p>Results of storage stability of extracts in ANADIAG validation study No. C1145 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer metabolites in Sugar beet.” showed a good stability of deltamethrin, trans-deltamethrin and alpha-R-isomer of deltamethrin residues in sugar beet leaves with top and sugar beet roots extracts for at least 15 days and 17 days respectively of frozen storage.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in roots were below LOD. Residues of deltamethrin in leaves with tops were found at the level 0.01 mg/kg.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2022, E. Thomas-Delille, Study code: C1149
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Sugar Beet raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 37.

One plot remained untreated.

Sampling was performed at maturity of the crop at BBCH 49 in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase.

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for deltamethrin and its alpha-R-isomer and trans-isomer in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)	
		Maturity, BBCH 49, (101 DAA)	
		Deltamethrin	Sum of Deltamethrin Trans-deltamethrin and alpha-R-isomer of deltamethrin
C1149 CZ1	Leaves with tops	0.01	0.01
	Roots	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 37	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Residue at harvest trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U, T	Maturity BBCH 49	Leaves with tops	From min. 12 plants
			Roots	

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units** / zones	Specimen size (kg)	Sampling to freezing time
C1149 CZ1 / UHL / A	11/10/2021	101	49	Leaves with tops	12 / 12	1.272	03h35
C1149 CZ1 / UHL / R	11/10/2021	101	49	Leaves with tops	12 / 12	1.262	03h35
C1149 CZ1 / UHR / A	11/10/2021	101	49	Roots	12 / 12	3.834	03h40
C1149 CZ1 / UHR / R	11/10/2021	101	49	Roots	12 / 12	3.884	03h40
C1149 CZ1 / THL / A	11/10/2021	101	49	Leaves with tops	12 / 12	1.266	03h10
C1149 CZ1 / THL / R	11/10/2021	101	49	Leaves with tops	12 / 12	1.264	03h10
C1149 CZ1 / THR / A	11/10/2021	101	49	Roots	12 / 12	3.426	03h35
C1149 CZ1 / THR / R	11/10/2021	101	49	Roots	12 / 12	3.444	03h35

*..... / A: Specimen for analysis

/ R: Spare specimen

DAA: Days After Application

**subsampling: leaves with tops and roots were quartered: 2 opposite quarters were sampled for analytical samples and 2 opposite quarters for retain samples.

1.3.6 Storage and shipment of the specimens to ANADIAG laboratory

Sample code	Storage time (days) ⁽¹⁾	Storage temperature	Date of Shipment to the lab.	Date of receipt at the lab.	Transport duration (days)	Temperature during transport
C1149 CZ1 / UHL / A	10	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾
C1149 CZ1 / UHR / A	10	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾
C1149 CZ1 / THL / A	10	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾
C1149 CZ1 / THR / A	10	Frozen ⁽²⁾	21/10/2021	22/10/2021	1	Frozen ⁽²⁾

⁽¹⁾ From sampling to shipment

⁽²⁾ Temperature was recorded during storage and transport

The /R samples were stored frozen at the field station and sent later to Anadiag laboratory.

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans-Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S512 02 11	Leaves with tops	NDR	NDR	NDR
S513 02 11	Roots	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans-Deltamethrin % Recovery	Alpha-R-isomer of deltamethrin % Recovery	Extraction date
S513 02 AA	Roots	0.01	65.0%	104.0%	70.9%	18/11/2021
S513 02 BA	Roots	0.01	65.6%	113.2%	76.4%	18/11/2021
S513 02 CA	Roots	0.10	74.0%	80.3%	76.6%	18/11/2021
S512 02 AA	Leaves with tops	0.01	72.2%	72.3%	73.3%	16/11/2021
S512 02 BA	Leaves with tops	0.01	88.9%	91.5%	99.9%	16/11/2021
S512 02 CA	Leaves with tops	0.10	70.3%	72.0%	70.6%	16/11/2021

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1149 CZ1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin And alpha-R-isomer of deltamethrin residues found (mg/kg)
C1149 01 01	C1149 CZ1 / UHL / A	-	Leaves with tops	-	NDR	NDR
C1149 01 02	C1149 CZ1 / UHR / A	-	Roots	-	NDR	NDR
C1149 01 03	C1149 CZ1 / THL / A	CHR//DEL 100 SC	Leaves with tops	101	0.01	0.01
C1149 01 04	C1149 CZ1 / THR / A	CHR//DEL 100 SC	Roots	101	NDR	NDR

DAA: Days After Application

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.4.4 Study 4

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in sugar beet samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 37, (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Northern France.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p>
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	<p>After extraction, samples were stored below -18°C and analysed after maximum 5 days for leaves with tops and 3 days for roots.</p> <p>Results of storage stability of extracts in ANADIAG validation study No. C1145 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer metabolites in Sugar beet.” showed a good stability of deltamethrin, trans-deltamethrin and alpha-R-isomer of deltamethrin residues in sugar beet leaves with top and sugar beet roots extracts for at least 15 days and 17 days respectively of frozen storage.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte. Residues of each analyte in all samples (roots and leaves with tops) were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:	KCA 6.3
Report	Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2022, E. Thomas-Delille, Study code: C1150
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Sugar Beet raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 37.

One plot remained untreated.

Samplings were performed just before application in the untreated plot, just after application in the treated plot, then 13 days after application and at BBCH 49 (at maturity of the crop) in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase..

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for deltamethrin and its alpha-R-isomer and trans-isomer in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)					
		Deltamethrin			Sum of Deltamethrin Trans-deltamethrin And alpha-R-isomer of deltamethrin		
		0 DAA	13 DAA	Maturity, BBCH 49 (103 DAA)	0 DAA	13 DAA	Maturity, BBCH 49 (103 DAA)
C1150 AN1	Leaves with tops	0.07	< LOQ	NDR	0.07	< LOQ	NDR
	Roots	NDR	NDR	NDR	NDR	NDR	NDR

DAA: Days After Application

< LOQ: Residues between LOD and LOQ

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR//DEL 100 SC	T1	BBCH 37	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR//DEL 100 SC.

1.1.1.2 Sampling Details

Decline curve trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U	0 DBA	Leaves with tops	From min. 12 plants
			Roots	
	T	0 DAA	Leaves with tops	From min. 12 plants
			Roots	
S2	U, T	14 (±1) DAA	Leaves with tops	From min. 12 plants
			Roots	
S3	U, T	Maturity BBCH 49	Leaves with tops	From min. 12 plants
			Roots	

DBA : Days before application

DAA : Days after application

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1150 AN1 / U0L / A	16/06/2021	0 DBA	37	Leaves with tops	18 / 18	3.31	04h45
C1150 AN1 / U0L / R	16/06/2021	0 DBA	37	Leaves with tops	18 / 18	3.35	04h45
C1150 AN1 / U0R / A	16/06/2021	0 DBA	37	Roots	18 / 18	1.11	04h45
C1150 AN1 / U0R / R	16/06/2021	0 DBA	37	Roots	18 / 18	1.03	04h45
C1150 AN1 / T0L / A	16/06/2021	0	37	Leaves with tops	18 / 18	3.45	03h00
C1150 AN1 / T0L / R	16/06/2021	0	37	Leaves with tops	18 / 18	3.54	03h00
C1150 AN1 / T0R / A	16/06/2021	0	37	Roots	18 / 18	1.11	03h00
C1150 AN1 / T0R / R	16/06/2021	0	37	Roots	18 / 18	1.20	03h00
C1150 AN1 / U14L / A	29/06/2021	13	39	Leaves with tops	12** / 12	2.50	02h15
C1150 AN1 / U14L / R	29/06/2021	13	39	Leaves with tops	12** / 12	2.74	02h15
C1150 AN1 / U14R / A	29/06/2021	13	39	Roots	12** / 12	2.23	02h15
C1150 AN1 / U14R / R	29/06/2021	13	39	Roots	12** / 12	2.28	02h15
C1150 AN1 / T14L / A	29/06/2021	13	39	Leaves with tops	12** / 12	2.38	01h40
C1150 AN1 / T14L / R	29/06/2021	13	39	Leaves with tops	12** / 12	2.68	01h40
C1150 AN1 / T14R / A	29/06/2021	13	39	Roots	12** / 12	1.89	01h40
C1150 AN1 / T14R / R	29/06/2021	13	39	Roots	12** / 12	1.84	01h40
C1150 AN1 / UHL / A	27/09/2021	103	49	Leaves with tops	12** / 12	4.73	01h30
C1150 AN1 / UHL / R	27/09/2021	103	49	Leaves with tops	12** / 12	4.93	01h30
C1150 AN1 / UHR / A	27/09/2021	103	49	Roots	12** / 12	3.95	01h30
C1150 AN1 / UHR / R	27/09/2021	103	49	Roots	12** / 12	3.86	01h30
C1150 AN1 / THL / A	27/09/2021	103	49	Leaves with tops	12** / 12	3.63	00h30
C1150 AN1 / THL / R	27/09/2021	103	49	Leaves with tops	12** / 12	4.09	00h30
C1150 AN1 / THR / A	27/09/2021	103	49	Roots	12** / 12	4.77	00h30
C1150 AN1 / THR / R	27/09/2021	103	49	Roots	12** / 12	4.49	00h30

*..... / A: Specimen for analysis
/ R: Spare specimen

DBA: Days Before Application

DAA: Days After Application

**subsampling: leaves with tops and roots were quartered: 2 opposite quarters were sampled for analytical samples and 2 opposite quarters for retain samples.

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans- Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S512 02 11	Leaves with tops	NDR	NDR	NDR
S513 02 11	Roots	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans- Deltamethrin % Recovery	Alpha-R- isomer of deltamethrin % Recovery	Extraction date
S513 02 AA	Roots	0.01	65.0%	104.0%	70.9%	18/11/2021
S513 02 BA	Roots	0.01	65.6%	113.2%	76.4%	18/11/2021
S513 02 CA	Roots	0.10	74.0%	80.3%	76.6%	18/11/2021
S512 02 AA	Leaves with tops	0.01	72.2%	72.3%	73.3%	18/11/2021
S512 02 BA	Leaves with tops	0.01	88.9%	91.5%	99.9%	18/11/2021
S512 02 CA	Leaves with tops	0.10	70.3%	72.0%	70.6%	18/11/2021

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1150 AN1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin And alpha-R-isomer of deltamethrin residues found (mg/kg)
C1150 01 01	C1150 AN1 / U0L / A	-	Leaves with tops	-	NDR	NDR
C1150 01 02	C1150 AN1 / U0R / A	-	Roots	-	NDR	NDR
C1150 01 03	C1150 AN1 / T0L / A	CHR//DEL 100 SC	Leaves with tops	0	0.07	0.07
C1150 01 04	C1150 AN1 / T0R / A	CHR//DEL 100 SC	Roots	0	NDR	NDR
C1150 01 05	C1150 AN1 / U14L / A	-	Leaves with tops	-	NDR	NDR
C1150 01 06	C1150 AN1 / U14R / A	-	Roots	-	NDR	NDR
C1150 01 07	C1150 AN1 / T14L / A	CHR//DEL 100 SC	Leaves with tops	13	< LOQ	< LOQ
C1150 01 08	C1150 AN1 / T14R / A	CHR//DEL 100 SC	Roots	13	NDR	NDR
C1150 01 09	C1150 AN1 / UHL / A	-	Leaves with tops	-	NDR	NDR
C1150 01 10	C1150 AN1 / UHR / A	-	Roots	-	NDR	NDR
C1150 01 11	C1150 AN1 / THL / A	CHR//DEL 100 SC	Leaves with tops	103	NDR	NDR
C1150 01 12	C1150 AN1 / THR / A	CHR//DEL 100 SC	Roots	103	NDR	NDR

DAA: Days After Application

< LOQ: Residues between LOD and LOQ

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.3.4.5 Study 5

Comments of zRMS:	<p>The objective of this study was to determine the residues of deltamethrin, its alpha-R-isomer and trans-isomer in sugar beet samples taken from the field trials following one application of CHR/I/DEL 100 SC at the rate of 0.05 L/ha (5 g deltamethrin/ha) at BBCH 37, (adjuvant (Asystent+) was added at the rate of 0.1 L/ha).</p> <p>The study was conducted in Germany.</p> <p>Residues were extracted with acetonitrile then cleaned-up. The extract obtained after centrifugation was then analysed by LC-MS/MS.</p> <p>After extraction, samples were stored below -18°C and analysed after maximum 5 days for leaves with tops and 2 days for roots.</p> <p>Results of storage stability of extracts in ANADIAG validation study No. C1145 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer metabolites in Sugar beet.” showed a good stability of deltamethrin, trans-deltamethrin and alpha-R-isomer of deltamethrin residues in sugar beet leaves with top and sugar beet roots extracts for at least 15 days and 17 days respectively of frozen storage.</p> <p>The limit of quantification (LOQ) was successfully established at 0.01 mg/kg for each analyte. The limit of detection (LOD) was 0.003 mg/kg for each analyte.</p> <p>Residues of each analyte in all samples (roots and leaves with tops) were below LOD.</p> <p>Stability studies for deltamethrin cover storage time.</p> <p>The study is accepted.</p>
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Reference:

KCA 6.3

Report

Determination of Deltamethrin and its alpha-R-isomer and trans-isomer Residues in Sugar Beet Following Foliar application with CHR/I/DEL 100 SC under Field Conditions in Northern Europe in 2021, 2022, E. Thomas-Delille C1151

Guideline(s):

Regulation (EC) No 1107/2009

Deviations:

Yes

GLP:

Yes

Acceptability:

Yes

Methods:

The objective of the study was to determine the residue levels of deltamethrin and its alpha-R-isomer and trans-isomer in Sugar Beet raw agricultural commodity after one foliar application of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L), at the rate of 0.05 L/ha.

The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at one site in Northern Europe. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest.

One plot was treated one time with CHR/I/DEL 100 SC at the application rate of 0.05 L/ha (5 g deltamethrin/ha) with 0.1 L/ha of adjuvant (Asystent+). The application was made at BBCH 37.

One plot remained untreated.

Samplings were performed just before application in the untreated plot, just after application in the treated plot, then 13 days after application and at BBCH 49 (at maturity of the crop) in both plots.

Deltamethrin and its alpha-R-isomer and trans-isomer residues were analysed in samples harvested during the field phase..

Summarized results:

SUMMARIZED RESULTS

Residues in control samples were non-detectable. The residue results for deltamethrin and its alpha-R-isomer and trans-isomer in the treated specimens are summarized below:

Trial No.	Matrix	Residues (mg/kg)					
		Deltamethrin			Sum of Deltamethrin Trans-deltamethrin And alpha-R-isomer of deltamethrin		
		0 DAA	13 DAA	Maturity, BBCH 49 (136 DAA)	0 DAA	13 DAA	Maturity, BBCH 49 (136 DAA)
C1151 BW1	Leaves with tops	0.07	< LOQ	NDR	0.07	< LOQ	NDR
	Roots	NDR	NDR	NDR	NDR	NDR	NDR

DAA: Days After Application

< LOQ: Residues between LOD and LOQ

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

Application data:

1.1.1.1 Application details

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/I/DEL 100 SC	T1	BBCH 37	0.05 L/ha	5 g/ha	200-400 L/ha (±10%)
	Asystent +*			0.1 L/ha	-	

*Adjuvant (Asystent+) to be added in the tank mix with the test item CHR/I/DEL 100 SC.

1.1.1.2 Sampling Details

Decline curve trial(s)

Sampling event	Plot	Timing	Matrix	Min. Sample size
S1	U	0 DBA	Leaves with tops	From min. 12 plants
			Roots	
	T	0 DAA	Leaves with tops	From min. 12 plants
			Roots	
S2	U, T	14 (±1) DAA	Leaves with tops	From min. 12 plants
			Roots	
S3	U, T	Maturity BBCH 49	Leaves with tops	From min. 12 plants
			Roots	

DBA : Days before application

DAA : Days after application

Sampling summary:

1.3.5 List of specimens sampled

Field Sample No.*	Sampling date	DAA	Growth stage (BBCH)	Matrix	Number of units / zones	Specimen size (kg)	Sampling to freezing time
C1151 BW1 / U0L / A	14/06/2021	0 DBA	37	Leaves with tops	12 / 12	1.39	05h15
C1151 BW1 / U0L / R	14/06/2021	0 DBA	37	Leaves with tops	12 / 12	1.40	05h15
C1151 BW1 / U0R / A	14/06/2021	0 DBA	37	Roots	12 / 12	0.43	05h15
C1151 BW1 / U0R / R	14/06/2021	0 DBA	37	Roots	12 / 12	0.48	05h15
C1151 BW1 / T0L / A	14/06/2021	0	37	Leaves with tops	12 / 12	1.39	04h05
C1151 BW1 / T0L / R	14/06/2021	0	37	Leaves with tops	12 / 12	1.43	04h05
C1151 BW1 / T0R / A	14/06/2021	0	37	Roots	12 / 12	0.35	04h05
C1151 BW1 / T0R / R	14/06/2021	0	37	Roots	12 / 12	0.36	04h05
C1151 BW1 / U14L / A	27/06/2021	13	38-39	Leaves with tops	12 / 12	3.67	04h05
C1151 BW1 / U14L / R	27/06/2021	13	38-39	Leaves with tops	12 / 12	3.64	04h05
C1151 BW1 / U14R / A	27/06/2021	13	38-39	Roots	12 / 12	2.16	03h35
C1151 BW1 / U14R / R	27/06/2021	13	38-39	Roots	12 / 12	1.94	03h35
C1151 BW1 / T14L / A	27/06/2021	13	38-39	Leaves with tops	12 / 12	4.57	03h20
C1151 BW1 / T14L / R	27/06/2021	13	38-39	Leaves with tops	12 / 12	4.28	03h20
C1151 BW1 / T14R / A	27/06/2021	13	38-39	Roots	12 / 12	2.12	02h45
C1151 BW1 / T14R / R	27/06/2021	13	38-39	Roots	12 / 12	2.50	02h45
C1151 BW1 / UHL / A	28/10/2021	136	49	Leaves with tops	> 12 / 12	4.98	01h55
C1151 BW1 / UHL / R	28/10/2021	136	49	Leaves with tops	> 12 / 12	5.93	01h55
C1151 BW1 / UHR / A	28/10/2021	136	49	Roots	24** / 12	7.30	03h00
C1151 BW1 / UHR / R	28/10/2021	136	49	Roots	24** / 12	7.10	03h00
C1151 BW1 / THL / A	28/10/2021	136	49	Leaves with tops	> 12 / 12	5.72	01h15
C1151 BW1 / THL / R	28/10/2021	136	49	Leaves with tops	> 12 / 12	5.08	01h15
C1151 BW1 / THR / A	28/10/2021	136	49	Roots	24** / 12	5.68	03h00
C1151 BW1 / THR / R	28/10/2021	136	49	Roots	24** / 12	5.10	03h00

*..... / A: Specimen for analysis

/ R: Spare specimen

DBA: Days Before Application

DAA: Days After Application

**subsampling: roots were quartered: 2 opposite quarters were sampled for analytical samples and 2 opposite quarters for retain samples.

Fortification procedure:

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Blank values

Sample ANADIAG No.	Matrix	Deltamethrin amount found (mg/kg)	Trans- Deltamethrin amount found (mg/kg)	Alpha-R-isomer of deltamethrin amount found (mg/kg)
S512 02 11	Leaves with tops	NDR	NDR	NDR
S513 02 11	Roots	NDR	NDR	NDR

NDR: No detectable residues (residues below the limit of detection)

Recoveries

Analytical Sample No.	Matrix	Fortification level (mg/kg)	Deltamethrin % Recovery	Trans- Deltamethrin % Recovery	Alpha-R- isomer of deltamethrin % Recovery	Extraction date
S513 02 AA	Roots	0.01	65.0%	104.0%	70.9%	18/11/2021
S513 02 BA	Roots	0.01	65.6%	113.2%	76.4%	18/11/2021
S513 02 CA	Roots	0.10	74.0%	80.3%	76.6%	18/11/2021
S512 02 AA	Leaves with tops	0.01	72.2%	72.3%	73.3%	16/11/2021
S512 02 BA	Leaves with tops	0.01	88.9%	91.5%	99.9%	16/11/2021
S512 02 CA	Leaves with tops	0.10	70.3%	72.0%	70.6%	16/11/2021

2.4 Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1151 BW1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Deltamethrin residues found (mg/kg)	Sum of Deltamethrin, Trans-deltamethrin and alpha-R-isomer of deltamethrin residues found (mg/kg)
C1151 01 01	C1151 BW1 / U0L / A	-	Leaves with tops	-	NDR	NDR
C1151 01 02	C1151 BW1 / U0R / A	-	Roots	-	NDR	NDR
C1151 01 03	C1151 BW1 / T0L / A	CHR/I/DEL 100 SC	Leaves with tops	0	0.07	0.07
C1151 01 04	C1151 BW1 / T0R / A	CHR/I/DEL 100 SC	Roots	0	NDR	NDR
C1151 01 05	C1151 BW1 / U14L / A	-	Leaves with tops	-	NDR	NDR
C1151 01 06	C1151 BW1 / U14R / A	-	Roots	-	NDR	NDR
C1151 01 07	C1151 BW1 / T14L / A	CHR/I/DEL 100 SC	Leaves with tops	13	< LOQ	< LOQ
C1151 01 08	C1151 BW1 / T14R / A	CHR/I/DEL 100 SC	Roots	13	NDR	NDR
C1151 01 09	C1151 BW1 / UHL / A	-	Leaves with tops	-	NDR	NDR
C1151 01 10	C1151 BW1 / UHR / A	-	Roots	-	NDR	NDR
C1151 01 11	C1151 BW1 / THL / A	CHR/I/DEL 100 SC	Leaves with tops	136	NDR	NDR
C1151 01 12	C1151 BW1 / THR / A	CHR/I/DEL 100 SC	Roots	136	NDR	NDR

DAA: Days After Application

< LOQ: Residues between LOD and LOQ

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg for each analyte

LOQ = 0.01 mg/kg for each analyte

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies submitted

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.5.1 Distribution of the residue in peel/pulp

No new studies submitted

A 2.2.5.2 Processing studies on a core set of representative processes

No new studies submitted

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies submitted

A 2.2.7 Other/Special Studies

A 2.2.7.1.1 Study 1

Comments of zRMS:	The study is accepted. Samples were analysed 14 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.
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Reference: KCA 6.10

Report Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamethrin formulation (CHR/I/DEL 100 SC) under semi field conditions in Northern Europe in 2021, Lefebvre, C., C1201, Anadiag, France

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
 SANTE/2020/12830, Rev.1
 SANTE/11956/2016 rev. 9

Deviations: Yes

GLP: Yes

Acceptability: Yes

Objective of the study

The objective of the study was to determine the residue levels of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) in honey and pollen from bees foraging on Phacelia following one foliar application at flowering of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L) together with the adjuvant ASYSTENT+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Northern Europe.

On this site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering, one tunnel was treated with CHR/I/DEL 100 SC at the nominal rate of 0.05 L product/ha (5 g deltamethrin /ha) and with the adjuvant Asystent+ at the nominal rate of 0.1 L product/ha. The second

tunnel was kept untreated.

At flowering stage, one honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) were determined by analysis.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOP PG 0115.

The specimen of honey was allowed to thaw at $\approx +4^{\circ}\text{C}$. After homogenization, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

After homogenization of the specimen of pollen, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

Extraction

Samples were analysed using an in-house Anadiag method validated under the Anadiag study No. C1199 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer in Honey and Pollen”.

Residues are extracted with acetonitrile and water. The extract obtained after centrifugation is then analysed by LC-MS/MS.

Fortification and control samples

LOD

The limit of detection (LOD) is 0.30 ng/mL (expressed as lowest calibration standard) corresponding to 0.003 mg/kg for honey and pollen.

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey and pollen.

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1201 MA1 – Deltamethrin

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Deltamethrin Residues found (mg/kg)
C1201 01 01	C1201 MA1 / UH / A	-	Honey	-	NDR
C1201 01 02	C1201 MA1 / TH / A	CHR//DEL 100 SC	Honey	Maturity	NDR
C1201 01 03	C1201 MA1 / UP / A	-	Pollen	-	NDR
C1201 01 04	C1201 MA1 / TP / A	CHR//DEL 100 SC	Pollen	Maturity	0.01

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

Table 2 TRIAL No. C1201 MA1 – Sum of deltmethrin, Trans-deltamethrin and alpha-R-isomer of deltamethin)

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Sum of deltmethrin, Trans + R-isomer Residues found (mg/kg)
C1201 01 01	C1201 MA1 / UH / A	-	Honey	-	NDR
C1201 01 02	C1201 MA1 / TH / A	CHR//DEL 100 SC	Honey	Maturity	NDR
C1201 01 03	C1201 MA1 / UP / A	-	Pollen	-	NDR
C1201 01 04	C1201 MA1 / TP / A	CHR//DEL 100 SC	Pollen	Maturity	0.01

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the

range of 70 – 110% and RSD ≤ 20% for average recovery.
 The limit of quantification of the method was established at 0.010 mg/kg for honey.
 The analytical method for determining the residues of acetamiprid meets the criteria of SANTE/2020/12830, Rev.2 in terms of precision, accuracy and uncertainty.

A 2.2.7.1.2 Study 2

Comments of zRMS:	The study is accepted. Samples were analysed 2 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.
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Reference:	KCA 6.10
Report	Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamethrin formulation (CHR/I/DEL 100 SC) under semi field conditions in Northern Europe in 2021, Lefebvre, C., C1202, Anadiag, France
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830, Rev.1 SANTE/11956/2016 rev. 9
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study was to determine the residue levels of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) in honey and pollen from bees foraging on Phacelia following one foliar application at flowering of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L) together with the adjuvant ASYSTENT+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Northern Europe.
 On this site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering, one tunnel was treated with CHR/I/DEL 100 SC at the nominal rate of 0.05 L product/ha (5 g deltamethrin /ha) and with the adjuvant Asystent+ at the nominal rate of 0.1 L product/ha. The second tunnel was kept untreated.
 At flowering stage, one honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) were determined by analysis.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOP PG 0115.
 The specimen of honey was allowed to thaw at $\approx +4^{\circ}\text{C}$. After homogenization, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.
 After homogenization of the specimen of pollen, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

Extraction

Samples were analysed using an in-house Anadiag method validated under the Anadiag study No. C1199 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer in Honey and Pollen”.
 Residues are extracted with acetonitrile and water. The extract obtained after centrifugation is then analysed by LC-MS/MS.

Fortification and control samples

LOD

The limit of detection (LOD) is 0.30 ng/mL (expressed as lowest calibration standard) corresponding to 0.003 mg/kg for honey and pollen.

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey and pollen.

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1202 PL1 – Deltamethrin

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Deltamethrin Residues found (mg/kg)
C1202 01 01	C1202 PL1 / UH / A	-	Honey	-	NDR
C1202 01 02	C1202 PL1 / TH / A	CHR//DEL 100 SC	Honey	Maturity	NDR
C1202 01 03	C1202 PL1 / UP / A	-	Pollen	-	NDR
C1202 01 04	C1202 PL1 / TP / A	CHR//DEL 100 SC	Pollen	Maturity	0.03

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

Table 2 TRIAL No. C1202 PL1 – Sum of Deltamethrin, Trans deltamethrin and alpha-R-isomer of deltamethrin

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Sum of deltamethrin and Trans + R-isomer Residues found (mg/kg)
C1202 01 01	C1202 PL1 / UH / A	-	Honey	-	NDR
C1202 01 02	C1202 PL1 / TH / A	CHR//DEL 100 SC	Honey	Maturity	NDR
C1202 01 03	C1202 PL1 / UP / A	-	Pollen	-	NDR
C1202 01 04	C1202 PL1 / TP / A	CHR//DEL 100 SC	Pollen	Maturity	0.03

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and $\text{RSD} \leq 20\%$ for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANTE/2020/12830, Rev.2 in terms of precision, accuracy and uncertainty.

A 2.2.7.1.3 Study 3

Comments of zRMS:	The study is accepted. Samples were analysed 29 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.
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Reference: KCA 6.10

Report Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamethrin formulation (CHR/I/DEL 100 SC) under semi field conditions in Southern Europe in 2021, Lefebvre, C., C1203, Anadiag, France

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
 SANTE/2020/12830, Rev.1
 SANTE/11956/2016 rev. 9

Deviations: Yes

GLP: Yes

Acceptability: Yes

Objective of the study

The objective of the study was to determine the residue levels of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) in honey and pollen from bees foraging on Phacelia following one foliar application at flowering of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L) together with the adjuvant ASYSTENT+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Southern Europe.

On this site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering, one tunnel was treated with CHR/I/DEL 100 SC at the nominal rate of 0.05 L product/ha (5 g deltamethrin /ha) and with the adjuvant Asystent+ at the nominal rate of 0.1 L product/ha. The second tunnel was kept untreated.

At flowering stage, one honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) were determined by analysis.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOP PG 0115.

The specimen of honey was allowed to thaw at $\approx +4^{\circ}\text{C}$. After homogenization, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

After homogenization of the specimen of pollen, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

Extraction

Samples were analysed using an in-house Anadiag method validated under the Anadiag study No. C1199 entitled “Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer in Honey and Pollen”.

Residues are extracted with acetonitrile and water. The extract obtained after centrifugation is then analysed by LC-MS/MS.

Fortification and control samples

LOD

The limit of detection (LOD) is 0.30 ng/mL (expressed as lowest calibration standard) corresponding to 0.003 mg/kg for honey and pollen.

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey and pollen.

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1203 EF1 – Deltamethrin

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Deltamethrin Residues found (mg/kg)
C1203 01 01	C1203 EF1 / UH / A	-	Honey	-	NDR
C1203 01 02	C1203 EF1 / TH / A	CHR//DEL 100 SC	Honey	Commercial Maturity	NDR
C1203 01 03	C1203 EF1 / UP / A	-	Pollen	-	NDR
C1203 01 04	C1203 EF1 / TP / A	CHR//DEL 100 SC	Pollen	Commercial Maturity	0.05

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

Table 2 TRIAL No. C1203 EF1 – Sum of Trans deltamethrin and alpha-R-isomer of deltamethrin)

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Sum of deltamethrin and Trans + R-isomer Residues found (mg/kg)
C1203 01 01	C1203 EF1 / UH / A	-	Honey	-	NDR
C1203 01 02	C1203 EF1 / TH / A	CHR//DEL 100 SC	Honey	Commercial Maturity	NDR
C1203 01 03	C1203 EF1 / UP / A	-	Pollen	-	NDR
C1203 01 04	C1203 EF1 / TP / A	CHR//DEL 100 SC	Pollen	Commercial Maturity	0.05

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANTE/2020/12830,Rev.2 in terms of precision, accuracy and uncertainty.

A 2.2.7.1.4 Study 4

Comments of zRMS:	The study is accepted. Samples were analysed 15 days after sampling. Storage stability data are not normally required for samples extracted and analysed within 30 days from sampling.
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Reference:	KCA 6.10
Report	Determination of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) Residues in Honey and Pollen Following Foliar Applications on Phacelia with Deltamethrin formulation (CHR/I/DEL 100 SC) under semi field conditions in Southern Europe in 2021, Lefebvre, C., C1204, Anadiag, France
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009) SANTE/2020/12830, Rev.1 SANTE/11956/2016 rev. 9
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study was to determine the residue levels of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) in honey and pollen from bees foraging on Phacelia following one foliar application at flowering of the formulated product CHR/I/DEL 100 SC (100 g deltamethrin/L) together with the adjuvant ASYSTENT+, under semi-field conditions.

Field phase description

The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Southern Europe.

On this site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering, one tunnel was treated with CHR/I/DEL 100 SC at the nominal rate of 0.05 L product/ha (5 g deltamethrin /ha) and with the adjuvant Asystent+ at the nominal rate of 0.1 L product/ha. The second tunnel was kept untreated.

At flowering stage, one honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of Deltamethrin (-cis) and its isomers (alpha-R-isomer and trans-isomer) were determined by analysis.

Initial sample preparation and homogenisation

The specimens were prepared according to ANADIAG SOP PG 0115.

The specimen of honey was allowed to thaw at $\approx +4^{\circ}\text{C}$. After homogenization, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

After homogenization of the specimen of pollen, the amount required by the analytical method (1 g) was weighed from this homogeneous matrix.

Extraction

Samples were analysed using an in-house Anadiag method validated under the Anadiag study No. C1199 entitled "Validation of the Analytical Method for the Analysis of Deltamethrin and its alpha-R-isomer and trans-isomer in Honey and Pollen".

Residues are extracted with acetonitrile and water. The extract obtained after centrifugation is then analysed by LC-MS/MS.

Fortification and control samples

LOD

The limit of detection (LOD) is 0.30 ng/mL (expressed as lowest calibration standard) corresponding to 0.003 mg/kg for honey and pollen.

LOQ

The limit of quantification (LOQ) was set at 0.01 mg/kg for honey and pollen.

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C1204 PH1 – Deltamethrin

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Deltamethrin Residues found (mg/kg)
C1204 01 01	C1204 PH1 / UH / A	-	Honey	-	NDR
C1204 01 02	C1204 PH1 / TH / A	CHR/I/DEL 100 SC	Honey	Maturity	NDR
C1204 01 03	C1204 PH1 / UP / A	-	Pollen	-	NDR
C1204 01 04	C1204 PH1 / TP / A	CHR/I/DEL 100 SC	Pollen	Maturity	0.07

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

Table 2 TRIAL No. C1204 PH1– Sum of deltamethrin, Trans deltamethrin and alpha-R-isomer of deltamethrin)

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Sum of deltamethrin, Trans + R-isomer Residues found (mg/kg)
C1204 01 01	C1204 PH1 / UH / A	-	Honey	-	NDR
C1204 01 02	C1204 PH1 / TH / A	CHR/I/DEL 100 SC	Honey	Maturity	NDR
C1204 01 03	C1204 PH1 / UP / A	-	Pollen	-	NDR
C1204 01 04	C1204 PH1 / TP / A	CHR/I/DEL 100 SC	Pollen	Maturity	0.07

NDR: No detectable residues (residues below the limit of detection)

LOD = 0.003 mg/kg / LOQ = 0.01 mg/kg

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 110% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for honey.

The analytical method for determining the residues of acetamiprid meets the criteria of SANTE/2020/12830,Rev.2 in terms of precision, accuracy and uncertainty.


Field phase summary- Residues in honey

Country (city) Year Trial No.	Commodity	Application					Residues (pyrimethanil)		
		Number of applications	Application rate g a.i./ha	L/ha	Growth stage (BBCH)	Date of applications	Sum of deltamethrin, Trans + R-isomer Commodity growth stage (BBCH)	DALA (days)	mg/kg
France 2022 C1201	Phacelia/ Stala	1	5.3	317	BBCH 65	18/08/2021	65	22	Honey= NDR
									Pollen= 0.01 mg/kg
Poland 2022 C1202	Phacelia/ Stala	1	4.9	293	BBCH 63-65	21/09/2021	63-65	28	Honey= NDR
									Pollen= 0.03 mg/kg
France 2022 C1203	Phacelia/ Stala	1	4.9	244	BBCH 65	18/08/2021	65	7	Honey= NDR
									Pollen= 0.05 mg/kg
France 2022 C1204	Phacelia/ Stala	1	5.0	300	BBCH 65	28/08/2021	65	11	Honey= NDR
									Pollen= 0.07 mg/kg


NDR: No detectable residues (residues below the limit of detection)

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations for acetamiprid

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		Acetamiprid (F)				Input values					
		LOGs (mg/kg) range from: _____ to: _____ Toxicological reference values ADI (mg/kg bw/day): 0.025 ARID (mg/kg bw): 0.025 Source of ADI: _____ Source of ARID: _____ Year of evaluation: _____ Year of evaluation: _____				Details - chronic risk assessment		Supplementary results - chronic risk assessment			
Comments:						Details - acute risk assessment/children		Details - acute risk assessment/adults			
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No. of diets exceeding the ADI: ---											
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	56%	NL toddler	14.09	48%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	37%	UK infant	9.16	31%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Eggs: Chicken		
	31%	FR toddler 2-3 yr	7.70	23%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	28%	FR child 3-15 yr	7.06	18%	Milk: Cattle	3%	Bovine: Muscle/meat	3%	Swine: Muscle/meat		
	27%	NL child	6.84	20%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	22%	UK toddler	5.44	17%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Wheat		
	20%	DE child	5.07	16%	Milk: Cattle	2%	Wheat	1%	Swine: Muscle/meat		
	20%	SE general	5.01	10%	Milk: Cattle	8%	Bovine: Muscle/meat	1%	Wheat		
	20%	DK child	4.95	10%	Milk: Cattle	4%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	18%	ES child	4.59	10%	Milk: Cattle	3%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	15%	FR infant	3.87	13%	Milk: Cattle	0.7%	Swine: Muscle/meat	0.7%	Bovine: Muscle/meat		
	15%	RO general	3.70	9%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Wheat		
	14%	DE general	3.58	10%	Milk: Cattle	2%	Swine: Muscle/meat	0.8%	Bovine: Muscle/meat		
	14%	DE women 14-50 yr	3.48	10%	Milk: Cattle	2%	Swine: Muscle/meat	0.9%	Wheat		
	13%	GEMS/Food G07	3.31	5%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Wheat		
	13%	GEMS/Food G15	3.19	6%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Wheat		
	12%	GEMS/Food G11	3.01	6%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Wheat		
	12%	GEMS/Food G08	2.98	4%	Milk: Cattle	4%	Swine: Muscle/meat	2%	Wheat		
	12%	NL general	2.96	7%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	11%	GEMS/Food G10	2.63	4%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	9%	ES adult	2.18	4%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		
	9%	IE adult	2.16	3%	Milk: Cattle	0.9%	Wheat	0.9%	Sheep: Liver		
	8%	DK adult	2.06	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	8%	FR adult	2.05	4%	Milk: Cattle	1%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	7%	GEMS/Food G06	1.65	3%	Wheat	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat		
	6%	LT adult	1.61	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.5%	Bovine: Muscle/meat		
	5%	UK adult	1.20	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		
	4%	IE child	1.02	3%	Milk: Cattle	0.5%	Wheat	0.3%	Swine: Muscle/meat		
	4%	UK vegetarian	0.94	3%	Milk: Cattle	0.8%	Wheat	0.3%	Eggs: Chicken		
	3%	IT toddler	0.81	3%	Wheat	0.6%	Other cereals				
	2%	IT adult	0.48	2%	Wheat	0.3%	Other cereals				
	2%	PT general	0.39	2%	Wheat		Grapes/fruits				
	0.6%	FI 3 yr	0.15	0.5%	Wheat	0.1%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products		
	0.5%	FI 6 yr	0.12	0.4%	Wheat	0.1%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products		
0.1%	FI adult	0.03	0.1%	Wheat	0.0%	Rapeseeds/canola seeds					
	Column 7				Grapes/fruits						
Conclusion: The estimated long-term dietary intake (TMDI/IEDI/IEDI) was below the ADI. The long-term intake of residues of Acetamiprid (F) is unlikely to present a public health concern.											

Acute risk assessment /children					Acute risk assessment / adults / general population					Acute risk assessment /children					Acute risk assessment / adults / general population				
Details - acute risk assessment /children					Details - acute risk assessment/adults					Hide IESTI new calculations					Show IESTI new calculations				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.										IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.									
Show results for all crops																			
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):						
	IESTI				IESTI				IESTI new				IESTI new						
	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)			
	33%	Milk: Cattle	0.2 / 0.2	25	31%	Milk: Cattle	0.2 / 0.2	7.7	33%	Milk: Cattle	0.2 / 0.2	25	31%	Milk: Cattle	0.2 / 0.2	7.7			
	32%	Bovine: Liver	1 / 1	8.1	16%	Bovine: Liver	1 / 1	4.0	32%	Bovine: Liver	1 / 1	8.1	16%	Bovine: Liver	1 / 1	4.0			
	29%	Bovine: Edible offals	1 / 1	7.3	15%	Milk: Goat	0.2 / 0.2	3.7	29%	Bovine: Edible offals	1 / 1	7.3	15%	Milk: Goat	0.2 / 0.2	3.7			
	22%	Swine: Muscle/meat	0.5 / 0.46	5.6	13%	Bovine: Edible offals	1 / 1	3.3	22%	Swine: Muscle/meat	0.5 / 0.46	5.6	13%	Bovine: Edible offals (other than	1 / 1	3.3			
	19%	Milk: Goat	0.2 / 0.2	4.8	13%	Swine: Other products	1 / 1	3.3	19%	Milk: Goat	0.2 / 0.2	4.8	13%	Swine: Other products	1 / 1	3.3			
	15%	Bovine: Kidney	1 / 1	3.8	12%	Milk: Sheep	0.2 / 0.2	3.0	15%	Bovine: Kidney	1 / 1	3.8	12%	Milk: Sheep	0.2 / 0.2	3.0			
	13%	Bovine: Muscle/meat	0.5 / 0.46	3.3	11%	Sheep: Liver	1 / 1	2.8	13%	Bovine: Muscle/meat	0.5 / 0.46	3.3	11%	Sheep: Liver	1 / 1	2.8			
Expand/collapse list																			
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)											
Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new):						
	IESTI				IESTI				IESTI new				IESTI new						
	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)			
	5%	Wheat / milling (flour)	0.1 / 0.1	1.2	2%	Wheat / bread/pizza	0.1 / 0.1	0.44	5%	Wheat / milling (flour)	0.1 / 0.1	1.2	2%	Wheat / bread/pizza	0.1 / 0.1	0.44			
	4%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	2%	Sugar beets (root) /	0.01 / 0.12	0.44	4%	Sugar beets (root) /	0.01 / 0.12	1.1	2%	Sugar beets (root) / sugar	0.01 / 0.12	0.44			
	2%	Wheat / milling (wholemeal)	0.1 / 0.1	0.55	2%	Wheat / pasta	0.1 / 0.1	0.38	2%	Wheat / milling (wholemeal)	0.1 / 0.1	0.55	2%	Wheat / pasta	0.1 / 0.1	0.38			
	0.9%	Rapeseeds / oils	0.4 / 0.8	0.24	1%	Wheat / bread	0.1 / 0.1	0.35	0.9%	Rapeseeds / oils	0.4 / 0.8	0.24	1%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35			
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!			
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!			
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!			



European Food Safety Authority
EFSA PRIMo revision 3.1: 2019/03/19

Acetamiprid (F)

LOD₂ (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day): **0.005** ARPD (mg/kg bw): **0.005**

Source of ADI: Source of ARPD:

Year of evaluation: Year of evaluation:

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults


Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI :								Exposure resulting from	
		8								MRLs set at the LOD (in % of ADI)	commodities not under assessment (in % of ADI)
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities		
TMDI/IEDI calculation (based on average food consumption)	280%	NL toddler	13.36	233%	Milk: Cattle	10%	Bovine: Muscle/meat	8%	Swine: Muscle/meat		
	173%	UK infant	8.35	155%	Milk: Cattle	11%	Bovine: Muscle/meat	5%	Eggs: Chicken		
	152%	FR toddler 2-3 yr	7.61	117%	Milk: Cattle	11%	Bovine: Muscle/meat	11%	Swine: Muscle/meat		
	139%	FR child 3-15 yr	6.94	91%	Milk: Cattle	14%	Bovine: Muscle/meat	14%	Swine: Muscle/meat		
	136%	NL child	6.73	38%	Milk: Cattle	10%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		
	108%	UK toddler	5.40	83%	Milk: Cattle	12%	Bovine: Muscle/meat	8%	Wheat		
	103%	DE child	5.14	73%	Milk: Cattle	8%	Wheat	5%	Swine: Muscle/meat		
	101%	SE general	5.03	50%	Milk: Cattle	40%	Bovine: Muscle/meat	6%	Wheat		
	33%	DK child	4.33	51%	Milk: Cattle	20%	Swine: Muscle/meat	12%	Bovine: Muscle/meat		
	31%	ES child	4.57	50%	Milk: Cattle	13%	Bovine: Muscle/meat	11%	Swine: Muscle/meat		
	77%	FR infant	3.87	67%	Milk: Cattle	3%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		
	74%	RO general	3.71	46%	Milk: Cattle	11%	Swine: Muscle/meat	10%	Wheat		
	72%	DE general	3.53	43%	Milk: Cattle	10%	Swine: Muscle/meat	4%	Bovine: Muscle/meat		
	70%	DE women 14-50 yr	3.49	50%	Milk: Cattle	8%	Swine: Muscle/meat	4%	Wheat		
	64%	GEMS/Food G07	3.18	26%	Milk: Cattle	11%	Swine: Muscle/meat	8%	Wheat		
	63%	GEMS/Food G15	3.13	28%	Milk: Cattle	13%	Swine: Muscle/meat	3%	Wheat		
	60%	GEMS/Food G11	3.00	31%	Milk: Cattle	11%	Swine: Muscle/meat	7%	Wheat		
	58%	GEMS/Food G08	2.95	22%	Milk: Cattle	18%	Swine: Muscle/meat	8%	Wheat		
	59%	NL general	2.94	34%	Milk: Cattle	3%	Swine: Muscle/meat	7%	Bovine: Muscle/meat		
	51%	GEMS/Food G10	2.57	22%	Milk: Cattle	8%	Bovine: Muscle/meat	8%	Swine: Muscle/meat		
	43%	ES adult	2.17	20%	Milk: Cattle	7%	Bovine: Muscle/meat	7%	Swine: Muscle/meat		
	43%	IE adult	2.16	17%	Milk: Cattle	5%	Wheat	5%	Sheep: Liver		
	41%	DK adult	2.05	21%	Milk: Cattle	8%	Swine: Muscle/meat	5%	Bovine: Muscle/meat		
	33%	FR adult	1.97	18%	Milk: Cattle	6%	Swine: Muscle/meat	6%	Bovine: Muscle/meat		
	32%	GEMS/Food G06	1.61	14%	Wheat	10%	Milk: Cattle	3%	Bovine: Muscle/meat		
	32%	LT adult	1.53	16%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	23%	UK adult	1.17	12%	Milk: Cattle	6%	Bovine: Muscle/meat	3%	Wheat		
	21%	IE child	1.03	14%	Milk: Cattle	2%	Wheat	2%	Swine: Muscle/meat		
	13%	UK vegetarian	0.94	13%	Milk: Cattle	4%	Wheat	1%	Eggs: Chicken		
	16%	IT toddler	0.81	13%	Wheat	3%	Other cereals				
10%	IT adult	0.48	8%	Wheat	1%	Other cereals					
8%	PT general	0.39	8%	Wheat		Grapefruits					
3%	FI 3 yr	0.16	2%	Wheat	0.6%	Rapeseeds/canola seeds	0.2%	Honey and other apiculture products			
3%	FI 6 yr	0.13	2%	Wheat	0.4%	Rapeseeds/canola seeds	0.2%	Honey and other apiculture products			
0.7%	FI adult	0.03	0.6%	Wheat	0.0%	Rapeseeds/canola seeds					
	Column 7					Grapefruits					

Conclusion:
The estimated TMDI/IEDI was in the range of 0 % to 273.6 % of the ADI.
For 8 diet(s) the ADI is exceeded.



European Food Safety Authority
EFSA PRIMo revision 3.1: 2019/03/19

Acetamiprid (F)

LOD₅ (mg/kg) range from: _____ to: _____

Toxicological reference values

ADI (mg/kg bw/day): **0.005** ARPD (mg/kg bw): **0.005**

Source of ADI: _____ Source of ARPD: _____

Year of evaluation: _____ Year of evaluation: _____

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:


Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI: 8						Exposure resulting from			
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MFRLs set at the LOD (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	280%	NL toddler	13.36	233%	Milk: Cattle	10%	Bovine: Muscle/meat	8%	Swine: Muscle/meat		
	173%	UK infant	8.35	155%	Milk: Cattle	11%	Bovine: Muscle/meat	5%	Eggs: Chicken		
	152%	FR toddler 2-3 yr	7.61	117%	Milk: Cattle	11%	Bovine: Muscle/meat	11%	Swine: Muscle/meat		
	133%	FR child 3-15 yr	6.94	91%	Milk: Cattle	14%	Bovine: Muscle/meat	14%	Swine: Muscle/meat		
	136%	NL child	6.73	38%	Milk: Cattle	10%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		
	108%	UK toddler	5.40	83%	Milk: Cattle	12%	Bovine: Muscle/meat	8%	Wheat		
	103%	DE child	5.14	73%	Milk: Cattle	8%	Wheat	5%	Swine: Muscle/meat		
	101%	SE general	5.03	50%	Milk: Cattle	40%	Bovine: Muscle/meat	6%	Wheat		
	33%	DK child	4.33	51%	Milk: Cattle	20%	Swine: Muscle/meat	12%	Bovine: Muscle/meat		
	31%	ES child	4.57	50%	Milk: Cattle	13%	Bovine: Muscle/meat	11%	Swine: Muscle/meat		
	77%	FR infant	3.87	67%	Milk: Cattle	3%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		
	74%	RO general	3.71	46%	Milk: Cattle	11%	Swine: Muscle/meat	10%	Wheat		
	72%	DE general	3.53	43%	Milk: Cattle	10%	Swine: Muscle/meat	4%	Bovine: Muscle/meat		
	70%	DE women 14-50 yr	3.49	50%	Milk: Cattle	8%	Swine: Muscle/meat	4%	Wheat		
	64%	GEMS/Food G07	3.18	26%	Milk: Cattle	11%	Swine: Muscle/meat	8%	Wheat		
	63%	GEMS/Food G15	3.13	28%	Milk: Cattle	13%	Swine: Muscle/meat	3%	Wheat		
	60%	GEMS/Food G11	3.00	31%	Milk: Cattle	11%	Swine: Muscle/meat	7%	Wheat		
	53%	GEMS/Food G08	2.95	22%	Milk: Cattle	18%	Swine: Muscle/meat	8%	Wheat		
	59%	NL general	2.94	34%	Milk: Cattle	3%	Swine: Muscle/meat	7%	Bovine: Muscle/meat		
	51%	GEMS/Food G10	2.57	22%	Milk: Cattle	8%	Bovine: Muscle/meat	8%	Swine: Muscle/meat		
	43%	ES adult	2.17	20%	Milk: Cattle	7%	Bovine: Muscle/meat	7%	Swine: Muscle/meat		
	43%	IE adult	2.16	17%	Milk: Cattle	5%	Wheat	5%	Sheep: Liver		
	41%	DK adult	2.05	21%	Milk: Cattle	8%	Swine: Muscle/meat	5%	Bovine: Muscle/meat		
	33%	FR adult	1.97	18%	Milk: Cattle	6%	Swine: Muscle/meat	6%	Bovine: Muscle/meat		
	32%	GEMS/Food G06	1.61	14%	Wheat	10%	Milk: Cattle	3%	Bovine: Muscle/meat		
	32%	LT adult	1.53	16%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	23%	UK adult	1.17	12%	Milk: Cattle	6%	Bovine: Muscle/meat	3%	Wheat		
	21%	IE child	1.03	14%	Milk: Cattle	2%	Wheat	2%	Swine: Muscle/meat		
	13%	UK vegetarian	0.94	13%	Milk: Cattle	4%	Wheat	1%	Eggs: Chicken		
	16%	IT toddler	0.81	13%	Wheat	3%	Other cereals				
	10%	IT adult	0.48	8%	Wheat	1%	Other cereals				
	8%	PT general	0.39	8%	Wheat		Grapefruits				
3%	FI 3 yr	0.16	2%	Wheat	0.6%	Rapeseeds/canola seeds	0.2%	Honey and other apiculture products			
3%	FI 6 yr	0.13	2%	Wheat	0.4%	Rapeseeds/canola seeds	0.2%	Honey and other apiculture products			
0.7%	FI adult	0.03	0.6%	Wheat	0.0%	Rapeseeds/canola seeds					
	Column 7					Grapefruits					

Conclusion:
The estimated TMDI/IEDI was in the range of 0 % to 273.6 % of the ADI.
For 8 diet(s) the ADI is exceeded.

A 3.2 IESTI/IEDI calculations for acetamiprid



European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Acetamidiprid (F)

LOGs (mg/kg) range from: _____ to: _____

Toxicological reference values

ADI (mg/kg bw/day): **0.025** ARfD (mg/kg bw): **0.025**

Source of ADI: _____ Source of ARfD: _____

Year of evaluation: _____ Year of evaluation: _____

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments: _____

Normal mode

Chronic risk assessment: JMPR methodology (IED/TMDI)


No of diets exceeding the ADI : ---										Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI(NED)/IED calculation (based on average food consumption)	53%	NL toddler	13.29	48%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	36%	UK infant	8.88	31%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Eggs: Chicken		
	29%	FR toddler 2-3 yr	7.37	23%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	26%	FR child 3-15 yr	6.57	18%	Milk: Cattle	3%	Bovine: Muscle/meat	3%	Swine: Muscle/meat		
	25%	NL child	6.20	20%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	20%	UK toddler	5.03	17%	Milk: Cattle	2%	Bovine: Muscle/meat	0.7%	Eggs: Chicken		
	19%	SE general	4.63	10%	Milk: Cattle	8%	Bovine: Muscle/meat	0.7%	Eggs: Chicken		
	19%	DE child	4.63	16%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Eggs: Chicken		
	18%	DK child	4.52	10%	Milk: Cattle	4%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	17%	ES child	4.15	10%	Milk: Cattle	3%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	15%	FR infant	3.78	13%	Milk: Cattle	0.7%	Swine: Muscle/meat	0.7%	Bovine: Muscle/meat		
	13%	DE general	3.35	10%	Milk: Cattle	2%	Swine: Muscle/meat	0.8%	Bovine: Muscle/meat		
	13%	DE women 14-50 yr	3.22	10%	Milk: Cattle	2%	Swine: Muscle/meat	0.6%	Bovine: Muscle/meat		
	13%	RO general	3.19	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.6%	Bovine: Muscle/meat		
	11%	GEMS/Food G07	2.63	5%	Milk: Cattle	2%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	11%	GEMS/Food G15	2.67	6%	Milk: Cattle	3%	Swine: Muscle/meat	0.9%	Bovine: Muscle/meat		
	11%	GEMS/Food G11	2.66	6%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	11%	NL general	2.64	7%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	10%	GEMS/Food G08	2.45	4%	Milk: Cattle	4%	Swine: Muscle/meat	0.8%	Bovine: Muscle/meat		
	9%	GEMS/Food G10	2.15	4%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	8%	DK adult	1.95	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	8%	ES adult	1.95	4%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		
	8%	IE adult	1.94	3%	Milk: Cattle	0.9%	Sheep: Liver	0.8%	Bovine: Muscle/meat		
	7%	FR adult	1.82	4%	Milk: Cattle	1%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	6%	LT adult	1.51	3%	Milk: Cattle	2%	Swine: Muscle/meat	0.5%	Bovine: Muscle/meat		
	4%	UK adult	1.03	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.2%	Eggs: Chicken		
	4%	GEMS/Food G06	0.93	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.3%	Sheep: Muscle/meat		
	4%	IE child	0.91	3%	Milk: Cattle	0.3%	Swine: Muscle/meat	0.2%	Swine: Fat tissue		
	3%	UK vegetarian	0.74	3%	Milk: Cattle	0.3%	Eggs: Chicken	0.0%	Wheat		
	0.1%	IT toddler	0.02	0.1%	Wheat	0.0%	Other cereals				
	0.1%	IT adult	0.01	0.0%	Wheat	0.0%	Other cereals				
	0.0%	PT general	0.01	0.0%	Wheat		Grapefruits				
	0.0%	FI 3 yr	0.01	0.0%	Wheat	0.0%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products		
	0.0%	FI 6 yr	0.00	0.0%	Wheat	0.0%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products		
	0.0%	FI adult	0.00	0.0%	Wheat	0.0%	Rapeseeds/canola seeds				
	Column7				Grapefruits						

Conclusion:
The estimated long-term dietary intake (TMDI/NED/IED) was below the ADI.
The long-term intake of residues of Acetamidiprid (F) is unlikely to present a public health concern.

Part B – Section 7 - Core Assessment

Applicant version

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):			
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	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
	33%	Milk: Cattle	0.2 / 0.2	25	31%	Milk: Cattle	0.2 / 0.2	7.7	33%	Milk: Cattle	0.2 / 0.2	25	31%	Milk: Cattle	0.2 / 0.2	7.7
	32%	Bovine: Liver	1 / 1	8.1	16%	Bovine: Liver	1 / 1	4.0	32%	Bovine: Liver	1 / 1	8.1	16%	Bovine: Liver	1 / 1	4.0
	23%	Bovine: Edible offals	1 / 1	7.3	15%	Milk: Goat	0.2 / 0.2	3.7	23%	Bovine: Edible offals	1 / 1	7.3	15%	Milk: Goat	0.2 / 0.2	3.7
	22%	Swine: Muscle/meat	0.5 / 0.46	5.6	13%	Bovine: Edible offals	1 / 1	3.3	22%	Swine: Muscle/meat	0.5 / 0.46	5.6	13%	Bovine: Edible offals (other than	1 / 1	3.3
	19%	Milk: Goat	0.2 / 0.2	4.8	13%	Swine: Other products	1 / 1	3.3	19%	Milk: Goat	0.2 / 0.2	4.8	13%	Swine: Other products	1 / 1	3.3
	15%	Bovine: Kidney	1 / 1	3.8	12%	Milk: Sheep	0.2 / 0.2	3.0	15%	Bovine: Kidney	1 / 1	3.8	12%	Milk: Sheep	0.2 / 0.2	3.0
Processed commodities	13%	Bovine: Muscle/meat	0.5 / 0.46	3.3	11%	Sheep: Liver	1 / 1	2.8	13%	Bovine: Muscle/meat	0.5 / 0.46	3.3	11%	Sheep: Liver	1 / 1	2.8
	13%	Other farmed animals:	0.5 / 0.46	3.2	10%	Bovine: Muscle	0.5 / 0.46	2.6	12%	Swine: Edible offals	1 / 1	3.0	10%	Bovine: Muscle	0.5 / 0.46	2.6
	12%	Swine: Edible offals	1 / 1	3.0	10%	Swine: Edible offals	1 / 1	2.6	11%	Equine: Muscle/meat	0.5 / 0.46	2.8	10%	Swine: Edible offals (other than	1 / 1	2.6
	11%	Equine: Muscle/meat	0.5 / 0.46	2.8	10%	Other farmed animals:	0.5 / 0.46	2.6	10%	Sheep: Muscle/meat	0.5 / 0.46	2.5	3%	Swine: Muscle/meat	0.5 / 0.46	2.2
	10%	Sheep: Muscle/meat	0.5 / 0.46	2.5	3%	Swine: Muscle/meat	0.5 / 0.46	2.2	10%	Eggs: Chicken	0.2 / 0.2	2.5	3%	Equine: Muscle/meat	0.5 / 0.46	2.2
	10%	Eggs: Chicken	0.2 / 0.2	2.5	3%	Equine: Muscle/meat	0.5 / 0.46	2.2	8%	Other farmed animals:	0.5 / 0.3	2.1	3%	Swine: Kidney	1 / 1	2.2
	5%	Swine: Kidney	1 / 1	1.3	3%	Swine: Kidney	1 / 1	2.2	6%	Wheat	0.1 / 0.1	1.4	3%	Sheep: Muscle/meat	0.5 / 0.46	2.2
	5%	Swine: Liver	1 / 1	1.2	3%	Sheep: Muscle/meat	0.5 / 0.46	2.2	5%	Swine: Kidney	1 / 1	1.3	8%	Bovine: Kidney	1 / 1	2.1
	3%	Milk: Sheep	0.2 / 0.2	0.71	8%	Bovine: Kidney	1 / 1	2.1	5%	Swine: Liver	1 / 1	1.2	8%	Bovine: Other products	1 / 1	2.0
	Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)								
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IESTI				IESTI				IESTI new				IESTI new				
Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	
1%	Sugar beets (root) / sugar	0.01 / 0.04	0.33	0.5%	Sugar beets (root) /	0.01 / 0.04	0.13	5%	Wheat / milling (flour)	0.1 / 0.1	1.2	2%	Wheat / bread/pizza	0.1 / 0.1	0.44	
0.1%	Wheat / milling (flour)	0.1 / 0	0.04	0.05%	Wheat / bread/pizza	0.1 / 0	0.01	4%	Sugar beets (root) /	0.01 / 0.12	1.1	2%	Sugar beets (root) / sugar	0.01 / 0.12	0.44	
0.1%	Wheat / milling (wholemeal)	0.1 / 0	0.02	0.05%	Wheat / pasta	0.1 / 0	0.01	2%	Wheat / milling	0.1 / 0.1	0.55	2%	Wheat / pasta	0.1 / 0.1	0.38	
0.0%	Rapeseeds / oils	0.4 / 0.03	0.01	0.04%	Wheat / bread	0.1 / 0	0.01	0.3%	Rapeseeds / oils	0.4 / 0.8	0.24	1%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35	
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EFSA PRIMo revision 3.1: 2019/03/19

Acetamidrid (F)

LOGs (mg/kg) range from: _____ to: _____

Toxicological reference values

ADI (mg/kg bw/day): **0.005** ARFD (mg/kg bw): **0.005**

Source of ADI: _____ Source of ARFD: _____

Year of evaluation: _____ Year of evaluation: _____

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments: _____

Normal mode


Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI: ---										Exposure resulting from MRLs set at the LOQ (in % of ADI)	
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)	
											TMDI/NEDI calculation (based on average food consumption)
22%	UK infant	1.09	15%	Milk: Cattle	5%	Eggs: Chicken	0.2%	Bovine: Muscle/meat			
17%	FR child 3-15 yr	0.83	9%	Milk: Cattle	5%	Eggs: Chicken	0.6%	Other farmed animals: Muscle/meat			
16%	FR toddler 2-3 yr	0.81	12%	Milk: Cattle	3%	Eggs: Chicken	0.2%	Bovine: Muscle/meat			
13%	NL child	0.67	10%	Milk: Cattle	2%	Eggs: Chicken	0.5%	Sugar beet roots			
13%	DE child	0.67	8%	Milk: Cattle	5%	Eggs: Chicken	0.3%	Poultry: Muscle/meat			
13%	UK toddler	0.64	8%	Milk: Cattle	4%	Eggs: Chicken	0.3%	Bovine: Muscle/meat			
10%	ES child	0.50	5%	Milk: Cattle	3%	Eggs: Chicken	0.7%	Other farmed animals: Muscle/meat			
10%	DK child	0.49	5%	Milk: Cattle	3%	Eggs: Chicken	0.4%	Swine: Muscle/meat			
10%	SE general	0.48	5%	Milk: Cattle	4%	Eggs: Chicken	0.3%	Bovine: Muscle/meat			
8%	RO general	0.41	5%	Milk: Cattle	3%	Eggs: Chicken	0.3%	Poultry: Muscle/meat			
8%	FR infant	0.40	7%	Milk: Cattle	0.7%	Eggs: Chicken	0.3%	Other farmed animals: Muscle/meat			
8%	IE adult	0.40	2%	Other farmed animals: Muscle/meat	2%	Sheep: Edible offals (other than liver and lungs)	2%	Milk: Cattle			
7%	DE women 14-50 yr	0.36	5%	Milk: Cattle	1%	Eggs: Chicken	0.3%	Sugar beet roots			
7%	DE general	0.36	5%	Milk: Cattle	1%	Eggs: Chicken	0.3%	Sugar beet roots			
6%	NL general	0.28	3%	Milk: Cattle	1%	Eggs: Chicken	0.2%	Swine: Muscle/meat			
5%	ES adult	0.26	2%	Milk: Cattle	2%	Eggs: Chicken	0.6%	Other farmed animals: Muscle/meat			
5%	FR adult	0.26	2%	Milk: Cattle	2%	Eggs: Chicken	0.5%	Other farmed animals: Muscle/meat			
4%	GEMS/Food G11	0.21	3%	Milk: Cattle	0.4%	Poultry: Muscle/meat	0.2%	Swine: Muscle/meat			
4%	GEMS/Food G15	0.21	3%	Milk: Cattle	0.4%	Poultry: Muscle/meat	0.3%	Swine: Muscle/meat			
4%	GEMS/Food G07	0.20	3%	Milk: Cattle	0.5%	Poultry: Muscle/meat	0.3%	Wheat			
4%	DK adult	0.20	2%	Milk: Cattle	1%	Eggs: Chicken	0.2%	Swine: Muscle/meat			
4%	GEMS/Food G10	0.18	2%	Milk: Cattle	0.6%	Poultry: Muscle/meat	0.2%	Wheat			
4%	GEMS/Food G08	0.18	2%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.4%	Poultry: Muscle/meat			
3%	LT adult	0.17	2%	Milk: Cattle	1%	Eggs: Chicken	0.2%	Swine: Muscle/meat			
3%	UK adult	0.14	1%	Eggs: Chicken	1%	Milk: Cattle	0.2%	Poultry: Muscle/meat			
3%	UK vegetarian	0.14	1%	Eggs: Chicken	1%	Milk: Cattle	0.1%	Wheat			
2%	IE child	0.11	1%	Milk: Cattle	0.6%	Eggs: Chicken	0.1%	Wheat			
2%	GEMS/Food G06	0.10	1.0%	Milk: Cattle	0.4%	Wheat	0.2%	Poultry: Muscle/meat			
0.5%	IT toddler	0.02	0.4%	Wheat	0.1%	Other cereals					
0.3%	IT adult	0.01	0.2%	Wheat	0.0%	Other cereals					
0.2%	PT general	0.01	0.2%	Wheat		Grapefruits					
0.1%	FI 3 yr	0.01	0.1%	Wheat	0.0%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products			
0.1%	FI 6 yr	0.00	0.1%	Wheat	0.0%	Rapeseeds/canola seeds	0.0%	Honey and other apiculture products			
0.0%	FI adult	0.00	0.0%	Wheat	0.0%	Rapeseeds/canola seeds					
	Column7	0.00	0.0%	Grapefruits							

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Acetamidrid (F) is unlikely to present a public health concern.


Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):			
	---				---				2				1			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
	64%	Other farmed animals:	0.5 / 0.46	3.2	52%	Swine: Edible offals	1 / 1	2.6	437%	Milk: Cattle	0.2 / 0.2	2.5	154%	Milk: Cattle	0.2 / 0.2	1.7
	60%	Swine: Edible offals	1 / 1	3.0	52%	Other farmed animals:	0.5 / 0.46	2.6	111%	Swine: Muscle/meat	0.5 / 0.46	5.6	74%	Milk: Goat	0.2 / 0.2	3.7
	50%	Milk: Cattle	0.2 / 0.02	2.5	17%	Eggs: Chicken	0.2 / 0.2	0.85	37%	Milk: Goat	0.2 / 0.2	4.8	60%	Milk: Sheep	0.2 / 0.2	3.0
	50%	Eggs: Chicken	0.2 / 0.2	2.5	15%	Milk: Cattle	0.2 / 0.02	0.77	75%	Bovine: Kidney	1 / 1	3.8	56%	Sheep: Liver	1 / 1	2.8
	10%	Milk: Goat	0.2 / 0.02	0.48	14%	Sheep: Edible offals	1 / 1	0.68	72%	Honey and other	1 / 1	3.6	52%	Bovine: Muscle	0.5 / 0.46	2.6
	7%	Bovine: Edible offals	0.05 / 0.05	0.36	3%	Poultry: Liver	0.1 / 0.1	0.47	66%	Bovine: Muscle/meat	0.5 / 0.46	3.3	52%	Swine: Edible offals (other than	1 / 1	2.6
7%	Poultry: Muscle/meat	0.02 / 0.02	0.34	7%	Milk: Goat	0.2 / 0.02	0.37	60%	Swine: Edible offals	1 / 1	3.0	44%	Swine: Muscle/meat	0.5 / 0.46	2.2	
6%	Honey and other	1 / 0.03	0.32	6%	Milk: Sheep	0.2 / 0.02	0.30	55%	Equine: Muscle/meat	0.5 / 0.46	2.8	44%	Equine: Muscle/meat	0.5 / 0.46	2.2	
5%	Bovine: Liver	0.03 / 0.03	0.24	6%	Eggs: Quail	0.2 / 0.2	0.28	50%	Sheep: Muscle/meat	0.5 / 0.46	2.5	44%	Swine: Kidney	1 / 1	2.2	
3%	Bovine: Kidney	1 / 0.04	0.15	5%	Poultry: Muscle	0.02 / 0.02	0.23	50%	Eggs: Chicken	0.2 / 0.2	2.5	44%	Sheep: Muscle/meat	0.5 / 0.46	2.2	
2%	Swine: Muscle/meat	0.5 / 0.01	0.12	3%	Bovine: Edible offals	0.05 / 0.05	0.17	41%	Other farmed animals:	0.5 / 0.3	2.1	42%	Bovine: Kidney	1 / 1	2.1	
2%	Poultry: Liver	0.1 / 0.1	0.11	3%	Poultry: Kidney	0.1 / 0.1	0.13	23%	Wheat	0.1 / 0.1	1.4	34%	Other farmed animals:	0.5 / 0.3	1.7	
1%	Bovine: Muscle/meat	0.5 / 0.01	0.07	2%	Honey and other	1 / 0.03	0.12	25%	Swine: Kidney	1 / 1	1.3	28%	Swine: Liver	1 / 1	1.4	
1%	Milk: Sheep	0.2 / 0.02	0.07	2%	Bovine: Liver	0.03 / 0.03	0.12	25%	Swine: Liver	1 / 1	1.2	28%	Honey and other apiculture	1 / 1	1.4	
1%	Equine: Muscle/meat	0.5 / 0.01	0.06	2%	Eggs: Goose	0.2 / 0.2	0.10	14%	Milk: Sheep	0.2 / 0.2	0.71	17%	Eggs: Chicken	0.2 / 0.2	0.85	
Expand/collapse list																
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)				2				
Processed commodities	Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):				Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
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	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
	7%	Sugar beets (root) / sugar	0.01 / 0.04	0.33	3%	Sugar beets (root) /	0.01 / 0.04	0.13	24%	Wheat / milling (flour)	0.1 / 0.1	1.2	3%	Wheat / bread/pizza	0.1 / 0.1	0.44
	0.7%	Wheat / milling (flour)	0.1 / 0	0.04	0.3%	Wheat / bread/pizza	0.1 / 0	0.01	22%	Sugar beets (root) /	0.01 / 0.12	1.1	3%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
	0.3%	Wheat / milling (wholemeal)	0.1 / 0	0.02	0.2%	Wheat / pasta	0.1 / 0	0.01	11%	Wheat / milling	0.1 / 0.1	0.55	8%	Wheat / pasta	0.1 / 0.1	0.38
	0.2%	Rapeseeds / oils	0.4 / 0.03	0.01	0.2%	Wheat / bread	0.1 / 0	0.01	5%	Rapeseeds / oils	0.4 / 0.8	0.24	7%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

A 3.3 TMDI calculations for deltamethrin

 <p>European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19</p>			<p align="center">Deltamethrin (F)</p>				<p align="center">Input values</p>					
			<p>LOGs (mg/kg) range from: to:</p>		<p align="center">Toxicological reference values</p>		<p>Details - chronic risk assessment</p>		<p>Supplementary results - chronic risk assessment</p>			
			<p>ADI (mg/kg bw/day): 0.01</p>		<p>ARfD (mg/kg bw): 0.01</p>		<p>Details - acute risk assessment/children</p>		<p>Details - acute risk assessment/adults</p>			
			<p>Source of ADI: Year of evaluation:</p>		<p>Source of ARfD: Year of evaluation:</p>							
<p>Comments:</p>												
<p>Normal mode</p>												
<p>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</p>												
			<p>No of diets exceeding the ADI : ---</p>							<p>Exposure resulting from</p>		
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOG (in % of ADI)	commodities not under assessment (in % of ADI)	
	81%	IT toddler	8.15	66%	Wheat	15%	Other cereals					
	75%	GEMS/Food G06	7.49	72%	Wheat	1%	Milk: Cattle	0.3%	Bovine: Muscle/meat			
	75%	NL toddler	7.47	39%	Wheat	30%	Milk: Cattle	2%	Rapeseeds/canola seeds			
	63%	FR child 3-15 yr	6.29	46%	Wheat	11%	Milk: Cattle	2%	Bovine: Muscle/meat			
	59%	RO general	5.89	51%	Wheat	6%	Milk: Cattle	1%	Swine: Muscle/meat			
	58%	NL child	5.85	41%	Wheat	12%	Milk: Cattle	1%	Swine: Muscle/meat			
	55%	DK child	5.54	44%	Wheat	6%	Milk: Cattle	3%	Swine: Muscle/meat			
TMDI/IEDI calculation (based on average food consumption)	55%	ES child	5.53	44%	Wheat	6%	Milk: Cattle	2%	Bovine: Muscle/meat			
	54%	GEMS/Food G15	5.38	45%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat			
	54%	DE child	5.36	42%	Wheat	10%	Milk: Cattle	0.7%	Swine: Muscle/meat			
	53%	UK toddler	5.25	39%	Wheat	10%	Milk: Cattle	2%	Bovine: Muscle/meat			
	50%	GEMS/Food G07	5.04	42%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat			
	49%	FR toddler 2-3 yr	4.95	31%	Wheat	15%	Milk: Cattle	2%	Bovine: Muscle/meat			
	49%	GEMS/Food G08	4.89	41%	Wheat	3%	Milk: Cattle	2%	Swine: Muscle/meat			
	49%	UK infant	4.86	26%	Wheat	19%	Milk: Cattle	2%	Bovine: Muscle/meat			
	48%	IT adult	4.84	41%	Wheat	7%	Other cereals					
	46%	GEMS/Food G10	4.59	39%	Wheat	3%	Milk: Cattle	1%	Bovine: Muscle/meat			
	44%	GEMS/Food G11	4.43	36%	Wheat	4%	Milk: Cattle	2%	Swine: Muscle/meat			
	44%	SE general	4.38	32%	Wheat	6%	Milk: Cattle	5%	Bovine: Muscle/meat			
	39%	PT general	3.92	39%	Wheat		Grapefruits					
	30%	DE women 14-50 yr	3.03	21%	Wheat	6%	Milk: Cattle	1%	Swine: Muscle/meat			
	29%	ES adult	2.87	23%	Wheat	2%	Milk: Cattle	0.9%	Bovine: Muscle/meat			
	28%	DE general	2.81	19%	Wheat	6%	Milk: Cattle	1%	Swine: Muscle/meat			
	28%	IE adult	2.77	23%	Wheat	2%	Milk: Cattle	0.5%	Sheep: Edible offals (other than liver)			
	27%	FR adult	2.70	22%	Wheat	2%	Milk: Cattle	0.8%	Swine: Muscle/meat			
	27%	NL general	2.69	19%	Wheat	4%	Milk: Cattle	1%	Swine: Muscle/meat			
	22%	UK vegetarian	2.24	20%	Wheat	2%	Milk: Cattle	0.1%	Bovine: Fat tissue			
	19%	UK adult	1.95	17%	Wheat	1%	Milk: Cattle	0.8%	Bovine: Muscle/meat			
	18%	FR infant	1.75	8%	Milk: Cattle	8%	Wheat	0.4%	Swine: Muscle/meat			
	17%	DK adult	1.72	11%	Wheat	3%	Milk: Cattle	1%	Swine: Muscle/meat			
	15%	LT adult	1.48	11%	Wheat	2%	Milk: Cattle	1%	Swine: Muscle/meat			
	15%	IE child	1.45	12%	Wheat	2%	Milk: Cattle	0.7%	Swine: Fat tissue			
	12%	FI 3 yr	1.21	12%	Wheat	0.2%	Rapeseeds/canola seeds					
	10%	FI 6 yr	0.98	10%	Wheat	0.1%	Rapeseeds/canola seeds					
	3%	FI adult	0.32	3%	Wheat	0.0%	Rapeseeds/canola seeds					
		Column7			Grapefruits		Grapefruits					

Acute risk assessment /children					Acute risk assessment / adults / general population					Acute risk assessment /children					Acute risk assessment / adults / general population					
Details - acute risk assessment /children					Details - acute risk assessment/adults					Hide IESTI new calculations					Show IESTI new calculations					
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.										IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.										
Show results for all crops																				
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):					Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):					IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):					IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):				
	1					---					1					---				
	IESTI					IESTI					IESTI new					IESTI new				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	144%	Wheat	1/1	14		84%	Wheat	1/1	8.4		144%	Wheat	1/1	14		84%	Wheat	1/1	8.4	
	62%	Milk: Cattle	0.05 / 0.05	6.2		13%	Milk: Cattle	0.05 / 0.05	1.3		62%	Milk: Cattle	0.05 / 0.05	6.2		28%	Other farmed animals: Muscle/meat	0.03 / 0.5	2.8	
	36%	Bovine: Edible offals	0.5 / 0.5	3.6		11%	Bovine: Edible offals (other	0.5 / 0.5	1.1		36%	Bovine: Edible offals	0.5 / 0.5	3.6		19%	Milk: Cattle	0.05 / 0.05	1.9	
	15%	Swine: Muscle/meat	0.03 / 0.12	1.5		13%	Swine: Edible offals (other	0.5 / 0.5	1.3		35%	Other farmed animals:	0.03 / 0.5	3.5		11%	Bovine: Edible offals (other than	0.5 / 0.5	1.1	
	15%	Swine: Edible offals (other	0.5 / 0.5	1.5		10%	Swine: Fat tissue	0.5 / 0.5	1.0		15%	Swine: Muscle/meat	0.03 / 0.12	1.5		13%	Swine: Edible offals (other than	0.5 / 0.5	1.3	
	12%	Milk: Goat	0.05 / 0.05	1.2		3%	Milk: Goat	0.05 / 0.05	0.32		15%	Swine: Edible offals (other	0.5 / 0.5	1.5		10%	Swine: Fat tissue	0.5 / 0.5	1.0	
10%	Bovine: Fat tissue	0.5 / 0.5	1.0		8%	Milk: Sheep	0.05 / 0.05	0.76		12%	Milk: Goat	0.05 / 0.05	1.2		3%	Milk: Goat	0.05 / 0.05	0.32		
3%	Bovine: Muscle/meat	0.03 / 0.12	0.89		7%	Bovine: Muscle	0.03 / 0.12	0.71		10%	Bovine: Fat tissue	0.5 / 0.5	1.0		8%	Milk: Sheep	0.05 / 0.05	0.76		
3%	Other farmed animals:	0.03 / 0.12	0.86		7%	Other farmed animals:	0.03 / 0.12	0.69		3%	Bovine: Muscle/meat	0.03 / 0.12	0.89		7%	Bovine: Muscle	0.03 / 0.12	0.71		
3%	Swine: Fat tissue	0.5 / 0.5	0.85		6%	Swine: Muscle/meat	0.03 / 0.12	0.60		3%	Swine: Fat tissue	0.5 / 0.5	0.85		6%	Swine: Muscle/meat	0.03 / 0.12	0.60		
7%	Equine: Muscle/meat	0.03 / 0.12	0.75		6%	Equine: Muscle/meat	0.03 / 0.12	0.60		7%	Equine: Muscle/meat	0.03 / 0.12	0.75		6%	Equine: Muscle/meat	0.03 / 0.12	0.60		
7%	Sheep: Muscle/meat	0.03 / 0.12	0.67		6%	Sheep: Muscle/meat	0.03 / 0.12	0.59		7%	Sheep: Muscle/meat	0.03 / 0.12	0.67		6%	Sheep: Muscle/meat	0.03 / 0.12	0.59		
5%	Poultry: Muscle/meat	0.02 / 0.03	0.48		5%	Bovine: Fat tissue	0.5 / 0.5	0.48		5%	Poultry: Muscle/meat	0.02 / 0.03	0.48		5%	Bovine: Fat tissue	0.5 / 0.5	0.48		
3%	Rapeseeds/canola seeds	0.2 / 0.2	0.28		3%	Sheep: Edible offals (other	0.5 / 0.5	0.34		3%	Rapeseeds/canola seeds	0.2 / 0.2	0.28		3%	Sheep: Edible offals (other than	0.5 / 0.5	0.34		
2%	Eggs: Chicken	0.02 / 0.02	0.25		3%	Poultry: Muscle	0.02 / 0.03	0.33		2%	Eggs: Chicken	0.02 / 0.02	0.25		3%	Poultry: Muscle	0.02 / 0.03	0.33		
Expand/collapse list																				
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)					1					Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)					1					
Processed commodities	Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI):					Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI):					Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):					Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):				
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	IESTI					IESTI					IESTI new					IESTI new				
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	121%	Wheat / milling (flour)	1/1	12		44%	Wheat / bread/pizza	1/1	4.4		121%	Wheat / milling (flour)	1/1	12		44%	Wheat / bread/pizza	1/1	4.4	
	55%	Wheat / milling (wholemeal)	1/1	5.5		38%	Wheat / pasta	1/1	3.8		55%	Wheat / milling	1/1	5.5		38%	Wheat / pasta	1/1	3.8	
	11%	Sugar beets (root) / sugar	0.01 / 0.12	1.1		35%	Wheat / bread (wholemeal)	1/1	3.5		11%	Sugar beets (root) / sugar	0.01 / 0.12	1.1		35%	Wheat / bread (wholemeal)	1/1	3.5	
	1%	Rapeseeds / oils	0.2 / 0.4	0.12		4%	Sugar beets (root) / sugar	0.01 / 0.12	0.44		1%	Rapeseeds / oils	0.2 / 0.4	0.12		4%	Sugar beets (root) / sugar	0.01 / 0.12	0.44	
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A 3.4 IESTI/IEDI calculations for deltamethrin

 <p>European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19</p>		Deltamethrin (F)		Input values							
		LOGs (mg/kg) range from: to:		<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>							
		Toxicological reference values									
		ADI (mg/kg bw/day): 0.01		ARfD (mg/kg bw): 0.01							
Source of ADI:		Source of ARfD:									
Year of evaluation:		Year of evaluation:									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---											
TMDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	33%	NL toddler	3.31	30%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		
	22%	UK infant	2.23	13%	Milk: Cattle	2%	Bovine: Muscle/meat	0.8%	Bovine: Edible offals (other than liver)		
	13%	FR toddler 2-3 yr	1.85	15%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		
	17%	FR child 3-15 yr	1.68	11%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	16%	NL child	1.60	12%	Milk: Cattle	1%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	13%	UK toddler	1.32	10%	Milk: Cattle	2%	Bovine: Muscle/meat	0.6%	Bovine: Fat tissue		
	12%	SE general	1.19	6%	Milk: Cattle	5%	Bovine: Muscle/meat	0.2%	Eggs: Chicken		
	12%	DE child	1.15	10%	Milk: Cattle	0.7%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		
	11%	DK child	1.13	6%	Milk: Cattle	3%	Swine: Muscle/meat	2%	Bovine: Muscle/meat		
	11%	ES child	1.10	6%	Milk: Cattle	2%	Bovine: Muscle/meat	2%	Swine: Muscle/meat		
	10%	FR infant	0.96	8%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		
	9%	DE general	0.90	6%	Milk: Cattle	1%	Swine: Muscle/meat	0.5%	Bovine: Muscle/meat		
	9%	DE women 14-50 yr	0.86	6%	Milk: Cattle	1%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		
	8%	GEMS/Food G11	0.83	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Swine: Fat tissue		
	8%	RO general	0.83	6%	Milk: Cattle	1%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		
	8%	GEMS/Food G15	0.81	4%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Swine: Fat tissue		
	8%	GEMS/Food G08	0.75	3%	Milk: Cattle	2%	Swine: Muscle/meat	1%	Swine: Fat tissue		
	7%	GEMS/Food G07	0.72	3%	Milk: Cattle	1%	Swine: Muscle/meat	1%	Bovine: Muscle/meat		
	7%	NL general	0.69	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		
	6%	GEMS/Food G10	0.63	3%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		
	6%	DK adult	0.60	3%	Milk: Cattle	1%	Swine: Muscle/meat	1.0%	Swine: Fat tissue		
	5%	ES adult	0.53	2%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.3%	Swine: Muscle/meat		
	5%	IE adult	0.48	2%	Milk: Cattle	0.5%	Sheep: Edible offals (other than liver and I)	0.5%	Bovine: Muscle/meat		
	5%	FR adult	0.47	2%	Milk: Cattle	0.8%	Swine: Muscle/meat	0.8%	Bovine: Muscle/meat		
	4%	LT adult	0.43	2%	Milk: Cattle	1%	Swine: Muscle/meat	0.7%	Swine: Fat tissue		
	3%	IE child	0.29	2%	Milk: Cattle	0.7%	Swine: Fat tissue	0.2%	Swine: Muscle/meat		
	3%	UK adult	0.27	1%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.1%	Bovine: Fat tissue		
	3%	GEMS/Food G06	0.25	1%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%	Sheep: Muscle/meat		
	2%	UK vegetarian	0.19	2%	Milk: Cattle	0.1%	Bovine: Fat tissue	0.1%	Eggs: Chicken		
0.2%	IT toddler	0.02	0.1%	Wheat	0.0%	Other cereals					
0.1%	IT adult	0.01	0.1%	Wheat	0.0%	Other cereals					
0.1%	PT general	0.01	0.1%	Wheat		Grapefruits					
0.0%	FI 3 yr	0.00	0.0%	Wheat	0.0%	Rapeseeds/canola seeds					
0.0%	FI 6 yr	0.00	0.0%	Wheat	0.0%	Rapeseeds/canola seeds					
0.0%	FI adult	0.00	0.0%	Wheat	0.0%	Rapeseeds/canola seeds					
0.0%	Column7	0.00	0.0%	Grapefruits		Grapefruits					

Acute risk assessment /children				Acute risk assessment / adults / general population				Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				Hide IESTI new calculations				Show IESTI new calculations				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.								IESTI new calculations: The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.								
Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):			
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	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	62%	Milk: Cattle	0.05 / 0.05	6.2	19%	Milk: Cattle	0.05 / 0.05	1.9	144%	Wheat	1 / 1	14	84%	Wheat	1 / 1	8.4
	36%	Bovine: Edible offals	0.5 / 0.5	3.6	17%	Bovine: Edible offals (other	0.5 / 0.5	1.7	62%	Milk: Cattle	0.05 / 0.05	6.2	28%	Other farmed animals: Muscle/meat	0.03 / 0.5	2.8
	15%	Swine: Muscle/meat	0.03 / 0.12	1.5	13%	Swine: Edible offals (other	0.5 / 0.5	1.3	36%	Bovine: Edible offals	0.5 / 0.5	3.6	19%	Milk: Cattle	0.05 / 0.05	1.9
	15%	Swine: Edible offals (other	0.5 / 0.5	1.5	10%	Swine: Fat tissue	0.5 / 0.5	1.0	35%	Other farmed animals:	0.03 / 0.5	3.5	17%	Bovine: Edible offals (other than	0.5 / 0.5	1.7
	12%	Milk: Goat	0.05 / 0.05	1.2	3%	Milk: Goat	0.05 / 0.05	0.32	15%	Swine: Muscle/meat	0.03 / 0.12	1.5	13%	Swine: Edible offals (other than	0.5 / 0.5	1.3
	10%	Bovine: Fat tissue	0.5 / 0.5	1.0	8%	Milk: Sheep	0.05 / 0.05	0.76	15%	Swine: Edible offals (other	0.5 / 0.5	1.5	10%	Swine: Fat tissue	0.5 / 0.5	1.0
3%	Bovine: Muscle/meat	0.03 / 0.12	0.89	7%	Bovine: Muscle	0.03 / 0.12	0.71	12%	Milk: Goat	0.05 / 0.05	1.2	3%	Milk: Goat	0.05 / 0.05	0.32	
3%	Other farmed animals:	0.03 / 0.12	0.86	7%	Other farmed animals:	0.03 / 0.12	0.69	10%	Bovine: Fat tissue	0.5 / 0.5	1.0	8%	Milk: Sheep	0.05 / 0.05	0.76	
3%	Swine: Fat tissue	0.5 / 0.5	0.85	6%	Swine: Muscle/meat	0.03 / 0.12	0.60	3%	Bovine: Muscle/meat	0.03 / 0.12	0.89	7%	Bovine: Muscle	0.03 / 0.12	0.71	
7%	Equine: Muscle/meat	0.03 / 0.12	0.75	6%	Equine: Muscle/meat	0.03 / 0.12	0.60	3%	Swine: Fat tissue	0.5 / 0.5	0.85	6%	Swine: Muscle/meat	0.03 / 0.12	0.60	
7%	Sheep: Muscle/meat	0.03 / 0.12	0.67	6%	Sheep: Muscle/meat	0.03 / 0.12	0.59	7%	Equine: Muscle/meat	0.03 / 0.12	0.75	6%	Equine: Muscle/meat	0.03 / 0.12	0.60	
5%	Poultry: Muscle/meat	0.02 / 0.03	0.48	5%	Bovine: Fat tissue	0.5 / 0.5	0.48	7%	Sheep: Muscle/meat	0.03 / 0.12	0.67	6%	Sheep: Muscle/meat	0.03 / 0.12	0.59	
2%	Eggs: Chicken	0.02 / 0.02	0.25	3%	Poultry: Edible offals (other	0.5 / 0.5	0.34	5%	Poultry: Muscle/meat	0.02 / 0.03	0.48	5%	Bovine: Fat tissue	0.5 / 0.5	0.48	
2%	Bovine: Liver	0.03 / 0.03	0.24	3%	Poultry: Muscle	0.02 / 0.03	0.33	3%	Rapeseeds/canola seeds	0.2 / 0.2	0.28	3%	Sheep: Edible offals (other than	0.5 / 0.5	0.34	
2%	Milk: Sheep	0.05 / 0.05	0.18	2%	Goat: Muscle	0.03 / 0.12	0.19	2%	Eggs: Chicken	0.02 / 0.02	0.25	3%	Poultry: Muscle	0.02 / 0.03	0.33	
Expand/collapse list																
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)				1				
Processed commodities	Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for children No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):				Results for adults No. of processed commodities for which ARfD/ADI is exceeded (IESTI new):			
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	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	3%	Sugar beets (root) / sugar	0.01 / 0.04	0.33	1%	Sugar beets (root) / sugar	0.01 / 0.04	0.13	121%	Wheat / milling (flour)	1 / 1	12	44%	Wheat / bread/pizza	1 / 1	4.4
	0.2%	Wheat / milling (flour)	1 / 0	0.02	0.03%	Wheat / bread/pizza	1 / 0	0.01	55%	Wheat / milling	1 / 1	5.5	38%	Wheat / pasta	1 / 1	3.8
	0.1%	Wheat / milling (wholesmeal)	1 / 0	0.01	0.06%	Wheat / pasta	1 / 0	0.01	11%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	35%	Wheat / bread (wholesmeal)	1 / 1	3.5
	0.0%	Rapeseeds / oils	0.2 / 0.01	0.00	0.07%	Wheat / bread (wholesmeal)	1 / 0	0.01	1%	Rapeseeds / oils	0.2 / 0.4	0.12	4%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
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Appendix 4 Additional information provided by the applicant