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| REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: A17960B  Product name(s): FORTENZA  Chemical active substance:  Cyantraniliprole, 600 g/L |
| Interzonal  Interzonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (New Authorization) |
| Applicant: Syngenta  Submission date: 30/10/2020  MS Finalisation date: August 2021 (initial Core Assessment)  December 2021 (final Core Assessment) |

Version history

|  |  |
| --- | --- |
| When | What |
| October 2020 | Initial dRR – Bayer submission |
| February 2021 | Update of GAP table for minor use (*Noctuinae*) |
| August 2021 | Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant , therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~. |
| December 2021 | Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~. |

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# Metabolism and residue data (KCA section 6)

## Summary and zRMS Conclusion

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comments:**  The application was for approval of Fortenza (A17960B), a FS formulation containing 600 g/L cyantraniliprole for uses as a seed treatment for maize and sweet corn.  **Maize** is the major crop in Northern Europe (EU guideline Document SANCO 7525/VI/95-rev.10.3 of 13 June 2017). For seed treatments 4 residue trials on maize are required.  **Sweet corn** is a minor crop in the Northern zone of Europe.  According to the SANCO 7525/VI/95-rev.10.3 of 13 June 2017 four trials on immature maize (maize harvested at BBCH stage 75, and in any case before BBCH stage 85) can be extrapolated to support sweet corn.  **Storage stability**  In EFSA Journal 2015;13(10):4263 it is stated that the stability of cyantraniliprole residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Regulation (EC) No 1107/2009 (EFSA, 2014). Residues of cyantraniliprole were found to be stable at ≤- 20°C for up to 24 months in high water-, high acid- and dry/starch content matrices and up to 18 months in high oil- and dry/protein content matrices.  Maize grain belongs to high starch content matrice, maize forage – high water contant matrice.  As the trial samples were stored for a maximum period of 7 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.  No additional data are required.  **Metabolism in plant**  According to the EFSA Journal 2014;12(9):3814:  *Metabolism studies were conducted on four crop categories; on cereals (rice), leafy crops (lettuce), pulses/oilseeds (cotton) and fruit crops (tomato). For each crop, metabolism was investigated after either three foliar applications or three soil drench applications at 150 g/ha (except for rice where a single soil application at 300 g/ha was experimented). Separate tests were conducted for soil applications, using 14C-cyantraniliprole either labelled on the cyano or pyrazole moieties, while foliar treatments were made using a mixture of both radiolabel forms in a 1:1 ratio. In this particular case, the use of mixed radiolabel forms was considered acceptable, since no extensive cleavage of the parent molecule was observed in the different studies.*  *In all plant matrices, total radioactive residue levels were at least one order of magnitude higher following foliar applications than soil drench applications. Irrespective of the mode of application, a similar metabolic profile was observed in the different crop groups, cyantraniliprole representing the major component of the residues, accounting for almost 25% to more than 90% TRR. Twenty different metabolites were identified, mostly below 5% TRR, the most abundant being the metabolite IN-J9Z38 representing 23% TRR at 32 day PHI in lettuce (0.007 mg/kg) and 6% to 28% TRR in rice foliage, straw and grain (0.03 to 0.09 mg/kg) following drench application.*  *All components identified in primary crops were also detected in the rotational crop studies conducted on wheat, soybean, redish and lettuce. As for primary crops, cyantraniliprole was identified as the main component of the residues in rotational crops (ca. 20% to 60% TRR). Several metabolites (IN-J9Z38, IN-JCZ38, IN-MLA84, IN-N7B69) were observed in proportions above 25% TRR in some plant matrices but representing less than 0.05 mg/kg. These rotational crop studies are however considered not fully appropriate to address the transfer of the soil metabolites in plants, as conducted with a single application, while the DT90 in soil were estimated to be in the range of 4 to 9 years for several metabolites and therefore, open to accumulation following several years of consecutive applications.*  Metabolism in rotational crops is similar to metabolism in primary crops.  The metabolism of cyantraniliprole in plants is sufficiently addressed to support the proposed uses of the product A17960B / Fortenza.  **Metabolism in livestock**  According to the EFSA Journal 2014;12(9):3814:  *“Goat and poultry metabolism studies conducted over 10 consecutive days at a feeding rate of 10 mg/kg feed were provided, using 14C-cyantraniliprole labelled either on the cyano or pyrazole moiety. The vast majority of administered radioactivity was excreted and less than 1% (poultry) and 2% (goat) of the radioactive residues were recovered in organs, tissues, milk or eggs. In addition to cyantraniliprole observed in all animal matrices, several other metabolites were identified in significant proportions and amounts in the different animal products; metabolites IN-J9Z38 and IN-MLA84 in eggs (13% to 27% TRR), metabolites IN-MYX98 and IN-N7B69 in milk (13% to 33% TRR). Based on these studies, the residue definition for products of animal origin was proposed as cyantraniliprole for monitoring and as the "sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69 expressed as cyantraniliprole" for risk assessment. An overall conversion factor of 2 (except for meat and honey were a conversion factor of 1 was derived) was derived from the animal feeding studies considering the metabolites relevant for each animal matrix. Having regard to the expected intakes calculated on the uses supported at EU level, the setting of MRLs for animal products was concluded to be not necessary.”*  No further data are required to support the proposed use.  **Residue definitions:**  **1.Plant residue definition**  The residue definition for plant for enforcement and for risk assessment is proposed as **cyantraniliprole** (EFSA Journal 2014;12(9):3814).  The current residue definition set in Regulation (EC) No 396/2005 (Regulation (EC) No 2020/856) is identical to the residue definition for enforcement derived in the peer review.  A separate residue definition for risk assessment is provided for processed commodities: **sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole**.  **2. Animal residue definition**  The residue definition for products of animal origin for enforcement assessment is proposed as **cyantraniliprole** and as the "**sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69 expressed as cyantraniliprole**" for risk assessment. An overall conversion factor of 2 (except for meat and honey were a conversion factor of 1 was derived) was derived from the animal feeding studies considering the metabolites relevant for each animal matrix (EFSA Journal 2014;12(9):3814).  **Magnitude of residues in plants**  New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application.  **Table 7.1: Summary of intended GAP in maize and sweet corn for cyantraniliprole.**   | Type of GAP | Method | Number of applications | Application rate per treatment (g as/ha) | Interval between application (days) | Growth stage at last application | PHI  (days) | | --- | --- | --- | --- | --- | --- | --- | | Intended GAP- maize | Seed treatment | 1 | 42.75 – 47.25 g ai/ha  450 µg as/seed | - | BBCH 00 | - | | Intended GAP- sweet corn | Seed treatment | 1 | 47.25 g ai/ha  450 µg as/seed | - | BBCH 00 | - |   Ten trials in Northern and Southern Europe were conducted to support the critical Syngenta use on maize. Cyantraniliprole 625 g/L FS was applied to maize seeds at a target rate of 750 μg as/seed. Residues of cyantraniliprole and metabolites found in treated whole plant samples collected at BBCH 75-81/82, cobs collected at BBCH 83-85 and mature grain and stover collected at commercial harvest.  Residues of cyantraniliprole in maize seed (kernels), cobs, plants and stover taken at normal commercial harvest were all below the limit of quantification (< 0.01 mg/kg).  Four trials were conducted in Southern Europe. Cyantraniliprole (SYN545377) was applied as a seed treatment at a rate of 0.6 mg cyantraniliprole / seed using A17960B, a flowable concentrate for seed treatment (FS) formulation containing 600 g cyantraniliprole / L. Treated maize samples were collected as whole plant at BBCH 39, 63 and 83-85 and whole cobs and remaining plant at BBCH 75-79 and 89. Samples were analysed for cyantraniliprole (SYN545377) and its metabolites, IN-N7B69 (M1), IN-JCZ38 (M2), IN-K5A79 (M3), IN-MYX98 (M4), IN-MLA84 (M5), IN-J9Z38 (M6) and IN-K7H19 (M7).  Residues of cyantraniliprole in all matrices were all below the limit of quantification (0.01 mg/kg).  The fourteen available trials are all overdosed with respect to the proposed GAP (600 or 750 µg a.s./seed vs the proposed GAP of 450 µg a.s./seed), but no residues of cyantraniliprole were found in any sample at or above the limit of quantification (LOQ; < 0.01 mg/kg). According to Regulation (EU) No 283/2013, in ‘<LOQ residue’ situation the number of studies to be performed may be reduced. The number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops. Therefore, the five trials in Northern Europe are sufficient to support the proposed use in Poland.  Treated samples for this study were stored at ca -18°C for less than 7 months between sampling and analysis. The study on the magnitude of residues is valid with regard to storage stability.  According to the SANCO 7525/VI/95 – rev.10.3 of 13 June 2017 four trials on immature maize (maize harvested at BBCH stage 75, and in any case before BBCH stage 85) can be extrapolated to support sweet corn.  Available results show that the in force MRL for cyantraniliprole on maize and sweet corn of 0.01 mg/kg (Regulation (EC) No 2020/856) will not be exceeded. Therefore the uses of A17960B / Fortenza can be considered as supported on maize and sweet corn in Central Europe.  The current EU MRLs for cyantraniliprole are sufficient to support the proposed uses.  No additional data are required.  **Industrial Processing and/or Household Preparation**  In EFSA Journal 2014;12(9):3814 it is stated that *Cyantraniliprole was stable under standard hydrolysis conditions simulating pasteurisation and sterilisation, but slightly degraded to IN-J9Z38 (12-14% AR) and to metabolites IN-N5M09 and IN-F6L99 (5-8% AR) resulting from the cleavage of the parent compound, under boiling conditions. Degradation under boiling conditions was confirmed in several processing studies where metabolite IN-J9Z38 was observed in significant higher levels than cyantraniliprole. The residue definitions in processed commodities were therefore proposed as "cyantraniliprole" for enforcement and as "sum of cyantraniliprole and IN-J9Z39 expressed as cyantraniliprole" for risk assessment. Data were sufficient to propose Processing Factors (PF) and Conversion Factors (CF) for a large number of processed commodities. Since metabolites IN-N5M09 and IN-F6L99 were observed in significant levels in some processed commodities (up to 0.09 mg/kg) additional data to address the toxicity of these two metabolites are requested.*  As quantifiable residues of cyantraniliprole are not expected in the treated crop, and the contribution of maize to the TMDI is <10%, there is no need to investigate the effect of industrial and/or household processing.  No additional data are required at the moment.  **Magnitude of residues in livestock**  Data presented by Applicant in point 7.2.3.3 have been accepted and are sufficient to support the proposed use on maize and sweet corn (seed treatment).  Livestock intake calculations and feeding studies cover all uses of cyantraniliprole in the EU. The calculated dietary burdens for dairy and beef cattle, and pig were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues has been performed in all relevant commodities of animal origin.  The conclusion presented by Applicant in point 7.2.3.5 : *The addition of maize grain, forage/silage, stover and processed commodities modifies the theoretical maximum daily intake for livestock, but regarding the available feeding data, the calculated MRLs for animal commodities are all < 0.01 mg/kg and there is no risk of animal MRLs being exceeded* has been accepted.  No additional data are required.  **Succeeding crops**  Rotational crop metabolism of lettuce, radish, wheat and soybean considered in the DAR. Metabolism in rotational crops is similar to metabolism in primary crops. In the EFSA Journal 2014;12(9):3814 it is stated that:  *“All components identified in primary crops were also detected in the rotational crop studies conducted on wheat, soybean, radish and lettuce. As for primary crops, cyantraniliprole was identified as the main component of the residues in rotational crops (ca. 20% to 60% TRR). Several metabolites (IN-J9Z38, IN-JCZ38, IN-MLA84, IN-N7B69) were observed in proportions above 25% TRR in some plant matrices but representing less than 0.05 mg/kg. These rotational crop studies are however considered not fully appropriate to address the transfer of the soil metabolites in plants, as conducted with a single application, while the DT90 in soil were estimated to be in the range of 4 to 9 years for several metabolites and therefore, open to accumulation following several years of consecutive applications…*  …*Numerous field rotational crop studies conducted in the USA with a total seasonal application rate of 450 g/ha were submitted (1N and 2.5N compared to indoor and outdoor EU GAPs). As for primary crops, samples were analysed for cyantraniliprole and 6 metabolites. For a Plant Back Interval (PBI) of 14 to 30 days, positive residues (>0.01 mg/kg) of cyantraniliprole, IN-J9Z38, IN-JCZ38 and IN-MLA84 were observed in most of the feed commodities. In contrast, in food commodities, cyantraniliprole only was detected in radish roots (up to 0.015 mg/kg) and in mature lettuce (0.033 mg/kg). For intermediate PBI of 120 to 180 days, only cyantraniliprole and IN-JCZ38 residues were detected, mostly in cereal and oilseed forage and hay at levels up to 0.05 mg/kg.* ***No residues above 0.01 mg/kg were measured in the one year PBI crops.*** *As mentioned above, since accumulation of several very persistent metabolites is expected following multiple years of consecutive applications, EFSA is of the opinion that the submitted trials conducted with a single seasonal application rate, are not fully appropriate to address the transfer of cyantraniliprole residues in rotational crops. Long term rotational crop studies considering cyantraniliprole and its most persistent metabolites are requested.”*  The rotational crop trials considered in the cyantraniliprole DAR indicate that residues of cyantraniliprole above the LOQ are not expected in rotational crops. However in EFSA Journal 2014;12(9):3814 it is stated that additional data to address the possible transfer in rotational crops, of the persistent soil metabolites, following multiple years of consecutive applications are required. Taking into account conclusions presented by EFSA in EFSA Journal 2014;12(9):3814, in our opinion to further mitigate risk of metabolites being uptaken by crops, it is considered appropriate to restrict the application of A17960B / Fortenza in accordance with the GAP to a maximum of once per year, in addition to stating that no other cyantraniliprole-containing products must be applied in the same year.  The crops under consideration can be grown in rotation.  The supported uses of cyantraniliprole in A17960B / Fortenza on maize and sweet corn includes seed treatment application (BBCH 00), therefore there is no likelihood of cyantranilprole exposure to honey bees and residues of cyantranilprole in pure blossom honey or other bee products will not occur from this use.  **Consumer risk assessment**  Considering the EFSA PRIMo 3.1 model and the MRLs proposed according to the EU uses, the highest TMDI was calculated to be 348% of the ADI (NL toddler; the highest contributor is apples with 86% of the ADI). Refined estimation using the STMRs derived from the supervised residue trials, results in a highest IEDI value of 81% of the ADI (NL toddler; the highest contributor is apples with 17% of the ADI).  No chronic intake consumer concern was identified.  Acute risk assessment not required as an ARfD is not necessary (EFSA, 2014).  **OVERALL CONCLUSION:**  There are sufficient data to support the uses of A17960B / Fortenza on maize and sweet corn at the intended GAP. The proposed uses of cyantraniliprole in the product A17960B / Fortenza do not represent unacceptable chronic risk for the consumer.  No further studies are required to support the proposed uses.  The authorisation for the uses of A17960B / Fortenza on maize and sweet corn at the proposed GAP may be recommended. |

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### 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 A17960B are presented in Table 7.1‑1. They have been selected from the individual GAPs in the EU for maize. A list of all intended uses within the EU is given in Part B, Section 0.

Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01\* mg/kg for cyantraniliprole for maize and sweet corn as laid down in Reg. (EU) 396/2005 (Reg. (EC) No 2020/856) is not expected.

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

As far as consumer health protection is concerned, zRMS-Poland agrees with the authorization of the intended use.

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

Data gaps

Noticed data gaps are: None

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| PPP (product name/code): | | | | Fortenza / A17960B | | | | | | Formulation type: | | | FS(a, b) | | | | |  | |
| Active substance 1: | | | | cyantraniliprole | | | | | | Conc. of as 1: | | | 600 g/L(c) | | | | |  | |
| Active substance 2: | | | | n/a | | | | | | Conc. of as 2: | | | n/a (c) | | | | |  | |
| Safener: | | | | n/a | | | | | | Conc. of safener: | | | n/a (c) | | | | |  | |
| Synergist: | | | | n/a | | | | | | Conc. of synergist: | | | na (c) | | | | |  | |
| Applicant: | | | | Syngenta | | | | | | Professional use: | | |  | | | | |  | |
| Zone(s): | | | | interzonal (d) | | | | | | Non professional use: | | |  | | | | |  | |
| Verified by MS: | | | | yes | | | | | |  | | |  | | | | |  | |
| Field of use: | | | | insecticide | | | | | |  | | |  | | | | |  | |
| 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, 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/synergist per ha  (f) | | **Conclusions** | |
|  |  |  | |  |  | Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | | mL product / seed unit | g of a.s./ 100 kg seeds  Cyantraniliprole | | g as/ha  Cyantraniliprole | Slurry volume ml/  100 kg seeds  min / max |  |  | |  | |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | | | | | |
| n/a |  |  | |  |  |  |  |  | |  |  | |  |  |  |  | |  | |
| 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) | | | | | | | | | | | | | | | | | | | |
| 1 | Poland | Maize [ZEAMX] (corn biofuel) | | F | Cutworm | Treatment of seeds | BBCH 00 | 1 | | 37.5 | 225.00 | | 45.00 | 375 ml formulated product / 100 kg | n/a | Seed unit: 50000  450 μg CYNT/ seed  Seeding density maximum 80.000-100.000 seeds/ha  TGW: 200 – 450 gr 1000seeds | | A | |
| 2 | Poland | Maize [ZEAMX] (corn grain) | | F | Cutworm | Treatment of seeds | BBCH 00 | 1 | | 37.5 | 225.00 | | 42.75 |  | n/a | Seed unit: 50000  450 μg CYNT/ seed  Seeding density maximum 80.000-95.000 seeds/ha  TGW: 200 – 450 gr 1000seeds | | A | |
| 3 | Poland | Maize [ZEAMX] (corn silage) | | F | Cutworm | Treatment of seeds | BBCH 00 | 1 | | 37.5 | 225.00 | | 47.25 |  | n/a | Seed unit: 50000  450 μg CYNT/ seed  Seeding density maximum 80.000-105.000 seeds/ha  TGW: 200 – 450 gr 1000seeds | | A | |
| Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | | | | | | | | |
| 4 | Poland | Sweet corn | | F | *cutworm - Agrotis spp.*  *Agriotes spp.*  *Noctuinae* | Treatment of seeds | BBCH 00 | 1 | | 37.5 | 225.00 | | 47.25 | 375 ml formulated product / 100 kg  maximum is 2L of slurry, 375ml of formulated product + 1625ml of water / 100 kg | n/a | Seed unit: 50000  450 μg CYNT/ seed  Seeding density maximum 80.000-105.000 seeds/ha  TGW: 200 – 450 gr 1000seeds | | A | |
| Minor uses according to Article 51 (interzonal uses) | | | | | | | | | | | | | | | | | | | |
| n/a |  |  | |  |  |  |  |  | |  |  | |  |  |  |  | |  | |

Explanation for Column 15 “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 |

### Summary of the evaluation

The preparation A17960B contains 600 g/L cyantraniliprole.

Table 7.1‑2: Toxicological reference values for the dietary risk assessment of cyantraniliprole

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
| --- | --- | --- | --- | --- | --- |
| Cyantraniliprole | | | | | |
| ADI | EFSA  Reg. (EU) 2016/1414 | 2014  2016 | 0.01 mg/kg bw/day | One year dog | 100 |
| ARfD | EFSA  Reg. (EU) 2016/1414 | 2014  2016 | Not applicable (not necessary) | | |

#### 

#### Summary for cyantraniliprole

Table 7.1‑3: Summary for cyantraniliprole

| 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? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1,2,3 | Maize | Yes | Yes (14 trials) | N/R | Yes | Yes | No | No |

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

As residues of cyantraniliprole do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been investigated taking into account the specific circumstances of the cGAP uses being considered here. The rotational crop trials considered in the cyantraniliprole DAR indicate that residues of cyantraniliprole above the LOQ are not expected in rotational crops. However in EFSA Journal 2014;12(9):3814 it is stated that additional data to address the possible transfer in rotational crops, of the persistent soil metabolites, following multiple years of consecutive applications are required. Taking into account conclusions presented by EFSA in EFSA Journal 2014;12(9):3814, in our opinion to further mitigate risk of metabolites being uptaken by crops, it is considered appropriate to restrict the application of A17960B / Fortenza in accordance with the GAP to a maximum of once per year, in addition to stating that no other cyantraniliprole-containing products must be applied in the same year.

Considering the dietary burden and based on the intended uses (maize and sweet corn: seed treatment), 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.

No new MRLs have been proposed.

No chronic and acute risk has been identified for maize and sweet corn. The uses of A17960B / Fortenza on proposed crops is therefore acceptable.

#### Summary for A17960B

Table 7.1‑4: Information on A17960B (KCA 6.8)

| Crop | PHI for A17960B  proposed by applicant | PHI/ Withholding period\* sufficiently supported for | PHI for A17960B  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- |
| Cyantraniliprole |
| Maize | NR | NR | NR | - |

NR: not relevant: seed treatment use

\* Purpose of withholding period to be specified

Table 7.1‑5: Waiting periods before planting succeeding crops

|  |  |  |
| --- | --- | --- |
| Waiting period before planting succeeding crops | | Overall waiting period proposed by zRMS for A17960B |
| Crop group | Led by cyantraniliprole |
| NR | NR | NR |

NR: not relevant

Assessment

## Cyantraniliprole

General data on cyantraniliprole are summarized in the table below (last updated 2016/07/12: SANTE/00111/2015 rev 1).

Table 7.2‑1: General information on cyantraniliprole

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Cyantraniliprole |
| IUPAC | 3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide |
| Chemical structure |  |
| Molecular formula | C19H14BrClN6O2 |
| Molar mass | 473.72 g/mol |
| Chemical group | Diamide |
| Mode of action (if available) | Exhibits larvicidal activity as an orally ingested toxicant by targeting and disrupting the Ca2+ balance, second generation ryanodine receptor, foliar and systemic activity |
| Systemic | Yes |
| Company (ies) | Syngenta, FMC (formerly DuPont) |
| Rapporteur Member State (RMS) | United Kingdom |
| Approval status | Approved  Date of (24/08/2016) [Regulation (EU) No 2016/1414](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474010400662&uri=CELEX:32016R1414)) |
| Restriction  (e.g. is restricted to use as “...”) | None |
| Review Report | SANTE/00111/2015 – rev. 1  (12/07/2016) |
| Current MRL regulation | [Regulation (EC) No 2020/856](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1592999849847&uri=CELEX:32020R0856) |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | None |
| EFSA Journal : Conclusion on the peer review | Yes (EFSA 2014) |
| Current MRL applications on intended uses | None |

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

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

Table 7.2‑2: Summary of stability data achieved at ≤ ‑ 18°C (unless stated otherwise)

| Commodity  category | Commodity | Acceptable maximum storage period | Report Reference | Source |
| --- | --- | --- | --- | --- |
| EU reviewed data | | | | |
| Plant products – cyantraniliprole | | | | |
| High water content | Apple | 24 months | Dupont-16990 Rev 1 | EFSA, 2014 |
| High acid content | Grape | 24 months |
| High oil content | Peanut | 18 months |
| High starch content | Potato | 24 months |
| High protein content | Dried beans | ~~24~~ 18 months |
| **Plant products – IN-J9Z38** | | | | |
| High water content | Apple | 24 months | Dupont-16990 Rev 1 | EFSA, 2014 |
| High acid content | Grape | 24 months |
| High oil content | Peanut | 24 months |
| High starch content | Potato | 24 months |
| High protein content | Dried beans | 24 months |
| Animal Products – cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N7B69 | | | | |
| Eggs | Poultry | 97 days | DuPont-27181 | United Kingdom, 2013 |
| Milk | Ruminant | 99 days | DuPont-27180, Revision No. 1 |
| Liver | Ruminant/Poultry | N/A | - |
| Muscle | Ruminant/Poultry | N/A | - |
| Fat | Ruminant/Poultry | N/A | - |

N/A: Not applicable – samples within the feeding studies were analysed within 30 days

Summary of plant metabolism studies reported in the EU

*Reference: EFSA, 2014*

“Cyantraniliprole and IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N7B69, IN-F6L99 and IN-N5M09 were shown to be stable at least 24 months in high water-, high acid-, high starch- and high protein-content matrices when stored frozen at -20°C (18 months for cyantraniliprole in high protein content matrices). In addition, most of the components were stable over two years in high oil-content matrices, except metabolite IN-N7B69 where a significant degradation was observed after a one year storage period, and for metabolites IN-JCZ38 and IN-K7H19 where recoveries after 1 month were below 70%.”

Conclusion on stability of residues during storage

The storage stability of cyantraniliprole and its relevant metabolites, IN-J9Z38, IN-MLA84, and IN‑N7B69 has been investigated in different groups, including eggs, milk, high water content, high acid content, high oil content, high starch content and high protein content commodities. Sufficient stability has been demonstrated to support the residue data presented in this submission.

#### Stability of residues in sample extracts (KCA 6.1)

Available data

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

Conclusion on stability of residues in sample extracts

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69 in sample extracts and fully support the residue data presented in the submission.

### Nature of residues in plants, livestock and processed commodities

#### Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data are 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 | | | | Report Reference | Source |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) (b) |
| EU reviewed data | | | | | | | | |
| Fruits and fruiting vegetables | Tomato | Mixture of [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole; 1:1 ratio | Foliar treatment, F | 150 g a.s./ha | 3 | Foliage:  0DAT1  7DAT1  0DAT2  7DAT2  0DAT3  7DAT3  14DAT3  Leaves and fruit:  125DAT3 | Dupont-16985 | EFSA, 2014 |
| [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole (one formulation for each label) | Soil (drench) treatment, F | 150 g a.s./ha | 3 | Foliage:  7DAT1  7DAT2  7DAT3  14DAT3  Leaves and fruit:  125DAT3 |

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

(b): DAT1 = Days After 1st Application

DAT2 = Days After 2nd Application

DAT3 = Days After 3rd Application

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) (b) |
| EU reviewed data | | | | | | | | |
| Leafy vegetables | Lettuce | Mixture of [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole; 1:1 ratio | Foliar treatment, F | 150 g a.s./ha | 3 | 0DAT1  7DAT1  0DAT2  7DAT2  0DAT3  7DAT3  14DAT3  32DAT3 | Dupont-16986 | EFSA, 2014 |
| [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole (one formulation for each label) | Soil (drench) treatment, F | 150 g a.s./ha | 3 | 7DAT1  7DAT2  7DAT3  14DAT3  32DAT3 |
| Pulses and oilseeds | Cotton | Mixture of [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole; 1:1 ratio | Foliar treatment, F | 150 g a.s./ha | 3 | Foliage:  0DAT1  7DAT1  0DAT2  7DAT2  0DAT3  7DAT3  13DAT3  Leaves and bolls:  124DAT3 | Dupont-16984, Rev 1 | EFSA, 2014 |
| [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole (one formulation for each label) | Soil (drench) treatment, F | 150 g a.s./ha | 3 | Foliage:  7DAT1  7DAT2  8DAT3  14DAT3  Leaves and bolls:  125DAT3 |

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

(b): DAT1 = Days After 1st Application

DAT2 = Days After 2nd Application

DAT3 = Days After 3rd Application

| Crop Group | Crop | Label position | Application and sampling details | | | | Report Reference | Source |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) (b) |
| EU reviewed data | | | | | | | | |
| Cereals | Rice | Mixture of [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole; 1:1 ratio | Foliar treatment, F | 150 g a.s./ha | 3 | Foliage:  0DAT1  7DAT1  7DAT2  7DAT3  14DAT3  Roots:  7DAT1  7DAT2  7DAT3  Straw, roots, grain (with bran):  140DAT1 | Dupont-18780 | EFSA, 2014 |
| [cyano-14C]-cyantraniliprole and [pyrazole carbonyl-14C]-cyantraniliprole (one formulation for each label) | Soil (granular) treatment, F | 300 g a.s./ha | 1 | Foliage:  3DAT  7DAT  14DAT  56DAT  Roots:  7DAT  56DAT  Straw, roots, grain (with bran):  175DAT |

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

(b): DAT1 = Days After 1st Application, DAT2 = Days After 2nd Application, DAT3 = Days After 3rd Application

Summary of plant metabolism studies reported in the EU

*Reference: EFSA, 2014*

“In all plant matrices, total radioactive residue levels were at least one order of magnitude higher following foliar applications than soil drench applications. Irrespective of the mode of application, a similar metabolic profile was observed in the different crop groups, cyantraniliprole representing the major component of the residues, accounting for almost 25% to more than 90% TRR. Twenty different metabolites were identified, mostly below 5% TRR, the most abundant being the metabolite IN-J9Z38 representing 23% TRR at 32 day PHI in lettuce (0.007 mg/kg) and 6% to 28% TRR in rice foliage, straw and grain (0.03 to 0.09 mg/kg) following drench application.

As cyantraniliprole was shown to be the major component of the radioactive residues in the different plant studies, the residue definition for monitoring was limited to cyantraniliprole only. The inclusion of additional metabolites in the residue definition for risk assessment was considered. Having regard to the low residue levels observed in the supervised residues trials where all samples were analysed for a total of 6 to 7 metabolites, it was proposed to limit the residue definition for risk assessment to cyantraniliprole only, considering that the additional contribution of these metabolites to the overall consumer intake would be negligible”.

Conclusion on metabolism in primary crops

The metabolism of cyantraniliprole in plants following foliar and soil application is sufficiently addressed to support the proposed uses of the product A17960B.

#### Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data are submitted 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 | | | | Report reference | Source |
| Method,  F or G(a) | Rate  (g a.s./ha) | Sowing intervals  (DAT) | Harvest  Intervals\* (DAT) |
| EU reviewed data | | | | | | | | |
| Root and tuber vegetables | Red beet | [pyrazole-14C]-cyantraniliprole | Bare soil,  G | 300 | 25  120 | - | DuPont-15513 | Scott M T, Swain R S, Young G A, 1996 (Pilot study; non-GLP)  EFSA, 2014 |
| Pulses and oilseeds | Soybean | [pyrazole carbonyl-14C]-cyantraniliprole | Bare soil,  G | 300 | 25  120 | - |
| Cereals | Spring wheat | [pyrazole carbonyl-14C]-cyantraniliprole | Bare soil,  G | 300 | 25  120 | - |
| Leafy vegetables | Lettuce | [cyano-14C]-cyantraniliprole | Bare soil,  G | 450 | 30  120 | - | DuPont-15778 | Chapleo S, Green M A, 2009  EFSA, 2014 |
| [pyrazole carbonyl-14C]-cyantraniliprole | Bare soil,  G | 450 | 30  120 | - |
| Root and tuber vegetables | Red beet | [cyano-14C]-cyantraniliprole | Bare soil,  G | 450 | 30  120 | - |
| [pyrazole carbonyl-14C]-cyantraniliprole | Bare soil,  G | 450 | 30  120 | - |
| Cereals | Spring wheat | [cyano-14C]-cyantraniliprole | Bare soil,  G | 450 | 30  120  365(b) | - |
| [pyrazole carbonyl-14C]-cyantraniliprole | Bare soil,  G | 450 | 30  120  365(b) | - |

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

(b) Lettuce and red beet sowings at 365 days were not conducted due to low residues determined at the earlier plant-back intervals

\* Crop raw agricultural commodities (RACs) were sampled at maturity

Summary of metabolism studies in rotational crops reported in the EU

*Reference: United Kingdom, 2013*

“When crops were grown in soil aged for various intervals (25/30, 120, or 365 days) after treatment with [14C]-cyantraniliprole (1.5 to 2.25N), transfer of cyantraniliprole and its metabolites to food commodities (wheat grain, soybeans seeds, lettuce, and red beet roots) ranged from 0.01 to 0.11 mg/kg.

Cyantraniliprole was the main residue in wheat grain and lettuce leaves, with two metabolites noted above 10% TRR ((IN-MYX98 in lettuce, IN-JCZ38 and IN-N7B69 in wheat grain). In soybean seed and beet root, TRR was low and no compound individually accounted for more than 0.01 mg/kg.

Transfer of cyantraniliprole and its metabolites to animal feed items was higher than observed in the commodities for human consumption (0.09 to 1.6 mg/kg TRR in animal feed).

The predominant residue in wheat chaff, forage, hay and straw and soybean foliage was parent. The same was observed for soybean pods, except for 25 days-long PBI in which IN-JCZ38 was more abundant than parent. Concentrations of minor metabolites (IN-DBC80, IN K5A79, IN MYX98, and IN N7B69) were below 0.01 mg/kg in all commodities.

The main metabolite detected in wheat forage was IN J9Z38, which accounted for more than 10% of the TRR but less than 0.05 mg/kg.

The main metabolites detected in wheat hay, were IN J9Z38, IN-K7H19 which accounted for more than 10% TRR and 0.05 mg/kg, even for 365 days-long PBI. IN-MLA84 was quantified above at concentrations 0.05 mg/kg, but did not account for more than 6.6 % TRR.

The main metabolites detected in wheat straw, were IN J9Z38, IN-K7H19, IN-MLA84, IN-JCZ38 and IN-JSE76, which accounted for more than 0.05 mg/kg. Each of these components was at least three times less abundant than the parent, which represented 22.9 to 44.8% TRR.

The main metabolites detected in soybean foliage, were IN-MLA84 and IN-JSE76, which accounted for more than 10 %TRR. None of these components was quantified above 0.05 mg/kg. The main metabolite detected in soybean pods was IN-JCZ38, which accounted for more than 10 %TRR, but was not quantified above 0.05 mg/kg.

IN-N7B69 glucoside conjugate (0.02-0.05 mg/kg) was the principal component in red beet foliage, whereas parent was not quantified in this commodity.

Information from the two confined rotational crop studies allows proposition of a metabolic pathway in cereals, pulses and oilseeds, root crops and leafy crops when sown as rotational crops. The metabolic fate of cyantraniliprole in these crops is complex with the formation of over 20 metabolites. The proposed pathway was included as part of the Global Review document already submitted.

In wheat, lettuce, red beets, and soybeans the cyano group underwent varying degrees of hydrolysis to amide and carboxylic acid (IN-K7H19, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, and IN-K5A79) moieties. Cyantraniliprole also cyclized and was dehydrated both with and without loss of the N-methyl group to form IN-J9Z38 and IN-MLA84 (the demethylated metabolite of IN-J9Z38). Demethylation, presumably via oxidation of the N-methyl group to a hydroxymethyl group (as in IN-MYX98) then oxidation to the carboxylic acid and eventual loss of carbon dioxide was also a pathway leading to IN-HGW87, the free amide of parent. Oxidation on the benzylic carbon of cyantraniliprole gave the hydroxymethyl metabolite IN-N7B69. Glucose conjugation of IN-N7B69 was also observed. Hydroxylated IN-MLA84 and bis hydroxy cyantraniliprole were also reported. IN-DBC80, formed by cleavage of the carboxamide linkage between the pyridine and phenyl rings, could be formed from parent or a number of metabolites”.

Conclusion on metabolism in rotational crops

The overall metabolism of cyantraniliprole in rotational crops (wheat, red beet, lettuce and soybean) was consistent with metabolism seen in the primary crops. No metabolite other than those identified in primary crops was found in rotational crops. Therefore, a specific residue definition for rotational crops is not deemed necessary.

#### Nature of residues in processed commodities (KCA 6.5.1)

Available data

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

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

| Conditions | Identified compound(s) (%) | Report reference | Source |
| --- | --- | --- | --- |
| EU reviewed data | | | |
| Pasteurisation (20 minutes, 90°C, pH 4) | [cyano-14C]-cyantraniliprole: cyantraniliprole (90.56%), IN-J9Z38 (4.40%),  IN-M5M09 (1.90%)  [pyrazole carbonyl-14C]-cyantraniliprole:  cyantraniliprole (89.23%), IN-J9Z38 (5.36%)  IN-F6L99 (1.71%) | Dupont-16989 | Lowrie C, 2005  EFSA, 2014 |
| Baking, boiling, brewing (60 minutes, 100°C, pH 5) | [cyano-14C]-cyantraniliprole: cyantraniliprole (74.54%), IN-J9Z38 (11.51%)  IN-N5M09 (8.41%)  [pyrazole carbonyl-14C]-cyantraniliprole:  cyantraniliprole (75.12%), IN-J9Z38 (13.64%)  IN-F6L99 (5.33%) |
| Sterilisation (20 minutes, 120°C, pH 6) | [cyano-14C]-cyantraniliprole: cyantraniliprole (93.58%), IN-J9Z38 (6.21%)  [pyrazole carbonyl-14C]-cyantraniliprole:  cyantraniliprole (91.49%), IN-J9Z38 (3.71%)  IN-F6L99 (0.12%) |

Summary of high temperature studies reported in the EU

*Reference: United Kingdom, 2013*

“Based on the data generated in this study, cyantraniliprole was slightly susceptible to hydrolysis under conditions representative of pasteurisation at 90°C for 20 min. in pH 4 solution; and sterilisation at 120°C for 20 min. in pH 6 solution, resulting in the formation in IN-J9Z38. Further degradation of cyantraniliprole occurred under hydrolytic conditions representative of baking, brewing, or boiling at 100°C for 60 min. in pH 5 solution, resulting in the formation of ON-J9Z38, IN-F6L99, and IN-N5M09. Minor components were detected but represented <1% AR.”

Conclusion on nature of residues in processed commodities

The nature of residues of cyantraniliprole in processed products has been investigated. Cyantraniliprole is susceptible to hydrolysis under conditions representative of pasteurisation and sterilisation, resulting in the formation of IN-J9Z38. Further degradation of cyantraniliprole occurred under hydrolytic conditions representative of baking, brewing, or boiling at 100°C for 60 min. in pH 5 solution, resulting in the formation of IN-J9Z38, IN-F6L99, and IN-N5M09. The residue definitions in processed commodities were therefore proposed as "*cyantraniliprole*" for enforcement and as "*sum of cyantraniliprole and IN-J9Z3~~9~~8 expressed as cyantraniliprole*" for risk assessment.

#### 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 | Fruit and fruiting vegetables (tomato)  Leafy vegetables (lettuce)  Pulses and oilseeds (cotton)  Cereals (rice)  Soil and foliar applications |
| Rotational crops covered | Leafy vegetables (lettuce)  Root and tuber vegetables (red beet)  Pulses and oilseeds (soybean)  Cereals (wheat) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Cyantraniliprole is slightly susceptible to hydrolysis under sterilization and pasteurization conditions, and further degraded to IN-J9Z38 (11.51-13.65% AR), IN-F6L99 (5.33%) and IN-N5M09 (8.41% AR) under boiling/baking/ brewing conditions |
| Residue pattern in processed commodities similar to pattern in raw commodities? | No  Residue definition in processed commodities:  sum of cyantraniliprole and IN-J9Z38 expressed as cyantraniliprole (EFSA, 2014) |
| Plant residue definition for monitoring | Cyantraniliprole (Regulation (EU) 2016/1414)  Regulation (EC) No 2020/856 |
| Plant residue definition for risk assessment | Cyantraniliprole (EFSA, 2014) |
| Conversion factor from enforcement to RA | Not applicable, for raw commodities  Proposed for some processed commodities |

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

Available data

No new data are 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 | | Report reference | Reference |
| Rate  (mg/kg bw/d) | Duration  (days) | Commodity | Time of samp­ling |
| EU reviewed data | | | | | | | | | |
| Lactating ruminants | Goat | [cyano-14C]-cyantraniliprole: | 1 | 0.44 | 14 | Milk | twice daily | Dupont-16987 | McLellan G., Vance, C., Lowrie, C., 2008  EFSA 2014 |
| Urine and faeces | once daily |
| Tissues | at sacrifice |
| [pyrazole carbonyl-14C]-cyantraniliprole | 1 | 0.44 | 14 | Milk | twice daily |
| Urine and faeces | once daily |
| Tissues | at sacrifice |
| Laying poultry | Hens | [cyano-14C]-cyantraniliprole: | 5 | 1.07 | 14 | Eggs | twice daily | Dupont-16988 | McLellan G., Lowrie, C., 2008  EFSA, 2014 |
| Excreta | once daily |
| Tissues | at sacrifice |
| [pyrazole carbonyl-14C]-cyantraniliprole | 5 | 1.07 | 14 | Eggs | twice daily |
| Excreta | once daily |
| Tissues | at sacrifice |

Summary of animal metabolism studies reported in the EU

*Reference: United Kingdom, 2013*

“The nature of cyantraniliprole residues in commodities of animal origin was investigated in 2 studies in lactating goats and laying hens using CN-14C and PC-14C labelled cyantraniliprole.

Following the repeated oral administration of radiolabelled cyantraniliprole to goats and laying hens (7 and 14 consecutive daily oral administration respectively, at a nominal dose of 10 mg/kg in the feed), a high proportion of the dose was eliminated in the excreta. There was no evidence of any significant accumulation of radioactivity in milk and eggs as plateau were observed in both studies.

In laying hens, a high proportion of the dose was eliminated in the excreta (97-99%). TRR found in fat and muscle accounted for less than 0.002 and 0.006 mg eq./kg and was therefore not further characterized. The major residue in egg whites are unchanged parent (0.08 mg/kg, 32-41% of the TRR), IN-J9Z38 (0.034-0.075 mg/kg, 17-29% of the TRR) and IN-MLA84 (0.037-0.049 mg/kg, 18-19% of the TRR). Same compounds are identified in egg yolks but at lower level (<0.02 mg/kg). Other metabolites (IN-HGW87, IN-K5A79, IN-MYX98, IN-NBC97, IN-JSE78 and IN-K5A77) were identified in eggs at levels comprised between <0.01 and 0.02 mg/kg. In liver cyantraniliprole is not present and any metabolites accounts for more than 0.01 mg/kg.

In lactating goat, residues were rapidly eliminated primarily in the excreta (94-96%). Unchanged parent was the major residue in faeces (67-71% of the total dose). The principal residue in milk, liver kidney, muscle and fat was parent accounting for 0.02-0.14 mg/kg. Milk components included IN-MYX98 (0.01-0.17 mg eq/kg), IN-K7H19, IN-JCZ38, IN-N7B69, IN-HGW87, IN-K5A78, IN-MLA84 and IN-J9Z38, each at 0.01 mg/kg. In kidney and muscle IN-MYX98 is also the only metabolite detected at significant level (above 0.01 mg/kg). In liver, IN-MYX98, INK5A77, IN-K5A78 and IN-MLA84 were identified at levels ranged from 0.01-0.029 mg/kg. The main metabolite in fat is IN-J9Z38 detected at levels up to 0.065 mg/kg.

The metabolism of cyantraniliprole in the rat was consistent with that of the lactating goat (ruminant) and laying hen.”

Conclusion on metabolism in livestock

The metabolism of cyantraniliprole in livestock is sufficiently addressed to support the proposed uses of the product A17960B.

#### 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 | Approx. 14 days in milk  Approx. 27 days in eggs |
| Animal residue definition for monitoring | Cyantraniliprole (Regulation (EU) 2016/1414)  Regulation (EC) No 2020/856 |
| Animal residue definition for risk assessment | Sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole (EFSA 2014) |
| Conversion factor | 2 (except for meat and honey: 1) (EFSA 2014) |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No |

### Magnitude of residues in plants (KCA 6.3)

#### 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.

The residue trials included in this submission support the critical Syngenta use.

Table 7.2‑9: Summary of EU reported and new data supporting the intended uses of A17960B and conformity to existing MRL

| Commodity | Source | Residue zone (N-EU) | Evaluation GAP Residue levels (mg/kg)(a) | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) | MRL compliance |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Maize grain | **Intended GAP** | **N-EU** | **cGAP: 450 µg as/seed (equivalent to 42.75 g ai/ha; 225g ai/100kg seed** | N/A | | | | |
| New trials | N-EU | Trials GAP: 750 µg as/seed  5 x < 0.01 |
| New trials | S-EU | Trials GAP: 750 µg as/seed  5 x < 0.01 |
| New trials | S-EU | Trials GAP: 600 µg as/seed  4 x < 0.01 |
| Overall supporting data for **interzonal** cGAP | N-EU, S-EU (combined dataset) | 14 x < 0.01 | < 0.01 | < 0.01 | 0.01\* | 0.01\* | Yes |
| Maize forage/ silage | **Intended GAP** | **N-EU** | **cGAP: 450 µg as/seed (equivalent to 47.25 g ai/ha; 225g ai/100kg seed** | N/A | | | | |
| New trials | N-EU | Trials GAP: 750 µg as/seed  5 x < 0.01 |
| New trials | S-EU | Trials GAP: 750 µg as/seed  5 x < 0.01 |
| New trials | S-EU | Trials GAP: 600 µg as/seed  4 x < 0.01 |
| Overall supporting data for **interzonal** cGAP | N-EU, S-EU (combined dataset) | 14 x < 0.01 | < 0.01 | < 0.01 | 0.01\* | N/A | N/A |
| Maize stover | **Intended GAP** | **N-EU** | **cGAP: 450 µg as/seed (equivalent to 45 g ai/ha; 225g ai/100kg seed** | N/A | | | | |
| New trials | N-EU | Trials GAP: 750 µg as/seed  5 x < 0.01 |
| New trials | S-EU | Trials GAP: 750 µg as/seed  5 x < 0.01 |
| New trials | S-EU | Trials GAP: 600 µg as/seed  4 x < 0.01 |
| Overall supporting data for **interzonal** cGAP | N-EU, S-EU (combined dataset) | 14 x < 0.01 | < 0.01 | < 0.01 | 0.01\* | N/A | N/A |

(a) Definition of residue for enforcement and risk assessment are the same: cyantraniliprole

N/A: not applicable \*: indicates an MRL set at the limit of quantification

#### Conclusion on the magnitude of residues in plants

*Maize*

Maize is a major crop in northern Europe (**SANCO 7525/VI/95 rev.10.3**) and normally requires eight residues trials in the zone.

Fourteen trials are available for the use of cyantraniliprole as a seed treatment on maize. Ten trials, five in northern Europe and five in southern Europe were conducted using maize seed treated with DPX-HGW86-750, a seed treatment (FS) formulation containing cyantraniliprole at 625 g a.s./L. A nominal application rate of 750 µg a.s./seed was used and the seeds were drilled following normal commercial practice at seed densities equivalent to 67.5 g a.s./ha (nominal). In these trials, residues of cyantraniliprole in maize seed (kernels), cobs, plants and stover taken at normal commercial harvest were all below the limit of quantification (< 0.01 mg/kg).

Four trials in southern Europe were conducted using maize seed treated with A17960B (the subject of this submission), a seed treatment (FS) formulation containing cyantraniliprole at 600 g a.s./L. A nominal application rate of 600 µg a.s./seed was used and the seeds were drilled following normal commercial practice at seed densities equivalent to 50 g a.s./ha (nominal). In these trials, residues of cyantraniliprole in maize seed (kernels), cobs, plants and stover taken at normal commercial harvest were all below the limit of quantification (< 0.01 mg/kg). Immature whole plant samples have been classed with forage and mature remaining plant samples have been classed with stover.

The fourteen available trials are all overdosed with respect to the proposed GAP (600 or 750 µg a.s./seed vs the proposed GAP of 450 µg a.s./seed), but no residues of cyantraniliprole were found in any sample at or above the limit of quantification (LOQ; < 0.01 mg/kg). Where residues are all below the LOQ, four trials are required for a major crop. Therefore, the five trials in northern Europe are sufficient to support the proposed use in Poland, and are supported by nine trials in southern Europe, including four conducted with the formulation for which this submission is made. Sufficient trials are available.

Samples were stored frozen for a maximum of ~~6~~ 7 months. Cyantraniliprole has been shown to be stable under these conditions in crops with high water content, high acid content, high oil content, high starch content and high protein content for at least 18 months.

Samples were analysed for cyantraniliprole using method Dupont-15736. This method has been reviewed previously in the EU and found acceptable for use in crops with high water content, high acid content, high oil content, high starch content and in dry crops such as stover.

The data submitted show that no exceedance of the MRL will occur. The proposed use on maize as a seed treatment is considered acceptable.

#### Magnitude of residues in livestock

#### Dietary burden calculation

The proposed use of A17960B on maize would not result in residues of cyantraniliprole in animal feed items.

However, the use of cyantraniliprole-containing products is widespread throughout all zones in the EU, therefore the possible transfer of residues in animal commodities from other registered uses should be considered.

Livestock intake calculations and feeding studies undertaken are provided below, and cover all uses of cyantraniliprole in the EU. These were performed using the EFSA 2017 methodology. The results of these calculations have been used to derive input values for animal commodities in the consumer risk assessment presented in Point 7.2.8 and Appendix 3.

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

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: cyantraniliprole | | | | |
| Corn (field) forage/silage | 0.01 | This submission | 0.01 | This submission |
| Corn (field) stover | 0.01 | This submission | 0.01 | This submission |
| Corn (pop) stover | 0.01 | This submission | 0.01 | This submission |
| Carrots (culls) | 0.01 | STMR  (EFSA 2015; 13(10):4263) | 0.01 | HR  (EFSA 2015; 13(10):4263) |
| Potatoes (culls) | 0.014 | STMR  (EFSA 2014; 12(9):3814) | 0.11 | HR  (EFSA 2014; 12(9):3814) |
| Swedes (roots) | 0.01 | STMR  (EFSA 2015; 13(10):4263) | 0.01 | HR  (EFSA 2015; 13(10):4263) |
| Turnips (roots) | 0.01 | STMR  (EFSA 2015; 13(10):4263) | 0.01 | HR  (EFSA 2015; 13(10):4263) |
| Maize (field) grain | 0.01 | This submission | 0.01 | This submission |
| Popcorn grain | 0.01 | This submission | 0.01 | This submission |
| Cotton (undelinted seed) | 0.16 | STMR  (FAO, 2015) | 0.16 | STMR  (FAO, 2015) |
| Soybean (seed) | 0.03 | STMR  (FAO, 2015) | 0.03 | STMR  (FAO, 2015) |
| Apple pomace (wet) | 0.16 | STMR x PF  = 0.16 x 1.03  (EFSA 2014; 12(9):3814) | 0.16 | STMR x PF  = 0.16 x 1.03  (EFSA 2014; 12(9):3814) |
| Canola (rape seed) (meal) | 0.008 | STMR x PF  = 0.077 x 0.1  (FAO, 2015) | 0.008 | STMR x PF  = 0.077 x 0.1  (FAO, 2015) |
| Citrus (dried pulp) | 0.08 | STMR x PFx CF  = 0.16 x 0.4 x 1.2  (EFSA 2014; 12(9):3814) | 0.08 | STMR x PFx CF  = 0.16 x 0.4 x 1.2  (EFSA 2014; 12(9):3814) |
| Corn (maize) milled by-products | 0.01 | This submission | 0.01 | This submission |
| Corn (maize) hominy meal | 0.01 | This submission | 0.01 | This submission |
| Corn (maize) gluten feed | 0.01 | This submission | 0.01 | This submission |
| Corn (maize) gluten meal | 0.01 | This submission | 0.01 | This submission |
| Cotton (meal) | 0.016 | STMR x PF  = 0.16 x 0.1  (FAO, 2015) | 0.016 | STMR x PF  = 0.16 x 0.1  (FAO, 2015) |
| Distillers grain (from corn) | 0.01 | This submission | 0.01 | This submission |
| Potato process waste | 0.014 | STMR  (EFSA 2014; 12(9):3814) | 0.014 | STMR  (EFSA 2014; 12(9):3814) |
| Potato, dried pulp | 0.014 | STMR  (EFSA 2014; 12(9):3814) | 0.014 | STMR  (EFSA 2014; 12(9):3814) |
| Rape seed (meal) | 0.008 | STMR x PF  = 0.077 x 0.1  (FAO, 2015) | 0.008 | STMR x PF  = 0.077 x 0.1  (FAO, 2015) |
| Rice (bran/pollard) | 0.01 | STMR x PF  = 0.01\* x 1.0  (EFSA 2016;14(4):4447) | 0.01 | STMR x PF  = 0.01\* x 1.0  (EFSA 2016;14(4):4447) |
| Soybean (meal) | 0.003 | STMR x PF  = 0.03 x 0.1  (FAO, 2015) | 0.003 | STMR x PF  = 0.03 x 0.1  (FAO, 2015) |
| Soybean hulls | 0.39 | STMR x default PF  = 0.03 x 13  (FAO, 2015) | 0.39 | STMR x default PF  = 0.03 x 13  (FAO, 2015) |
| Sunflower (meal) | 0.007 | STMR x PF  = 0.067 x 0.1  (FAO, 2015) | 0.007 | STMR x PF  = 0.067 x 0.1  (FAO, 2015) |

Cyantraniliprole falls under old data requirements, therefore the only categories considered are dairy and beef cattle, laying poultry and pig. The results of the calculations are reported in Table 7.2-11. The calculated dietary burdens for dairy and beef cattle, and pig were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues has been performed in all relevant commodities of animal origin.

Table 7.2‑11: Results of the dietary burden calculation

| Animal species | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Maximum dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
| --- | --- | --- | --- | --- | --- |
| Risk assessment residue definition: sum cyantraniliprole, IN-J9Z38, IN-MLA84 and IN-N7B69, expressed as cyantraniliprole | | | | | |
| Beef cattle\* | 0.003 | 0.006 | Potato culls | 0.26 | Y |
| Dairy cattle\* | 0.004 | 0.009 | Potato culls | 0.24 | Y |
| Ram/ewe | - | - | - | - | - |
| Lamb | - | - | - | - | - |
| Breeding swine | - | - | - | - | - |
| Finishing swine\* | 0.003 | 0.010 | Potato culls | 0.33 | Y |
| Broiler poultry | - | - | - | - | - |
| Layer poultry\* | 0.003 | 0.006 | Potato culls | 0.09 | Y |
| Turkey | - | - | - | - | - |

\* These categories correspond to those (formerly) assessed at EU level.

#### Livestock feeding studies (KCA 6.4.1-6.4.3)

A summary of the values derived from the ruminant feeding study is presented in Table 7.2-12.

Table 7.2‑12: Summary of the outcome of livestock and poultry feeding studies

| Matrix | STMR (mg/kg )(a) | HR (mg/kg)(b) | MRL (mg/kg) | CF for RA |
| --- | --- | --- | --- | --- |
| Enforcement residue definition: cyantraniliprole | | | | |
| Poultry muscle | < 0.001 | < 0.001 | 0.01\* | 1.0 |
| Poultry fat | < 0.001 | < 0.001 | 0.01\* | 2.0 |
| Poultry liver | < 0.001 | 0.002 | 0.01\* | 1.7 |
| Eggs | 0.001 | 0.002 | 0.01\* | 1.9 |
| Ruminant muscle | <0.001 | <0.001 | 0.01\* | 1.0 |
| Ruminant fat | 0.001 | 0.002 | 0.01\* | 1.5 |
| Ruminant liver | 0.002 | 0.007 | 0.01\* | 1.7 |
| Ruminant kidney | 0.001 | 0.003 | 0.01\* | 2.0 |
| Ruminant milk | 0.001 | 0.002 | 0.01\* | 2.0 |

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues) according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

Available data

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

Table 7.2‑13: Overview of the values derived from livestock feeding studies

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue  (mg/kg)(b) | Highest residue  (mg/kg)(c) | Calculated MRL  (mg/kg) | CF for RA(d) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d)(a) | No | Result for enforcement | | Result for RA | |
| Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) |
| EU reviewed data (United Kingdom, 2013) | | | | | | | | | | | | |
| Enforcement residue definition: cyantraniliprole | | | | | | | | | | | | |
| Ruminant muscle | 0.004 | 0.009 | 0.09 | 3 | <0.01 | 0.01 | 0.01 | 0.01 | 0.001 | 0.001 | 0.01\* | 1.0 |
| 0.28 | 3 | 0.03 | 0.04 | 0.03 | 0.04 |
| 0.82 | 3 | 0.07 | 0.09 | 0.09 | 0.12 |
| Ruminant fat | 0.004 | 0.009 | 0.09 | 3 | 0.01 | 0.02 | 0.03 | 0.03 | 0.001 | 0.002 | 0.01\* | 1.5 |
| 0.28 | 3 | 0.04 | 0.07 | 0.07 | 0.11 |
| 0.82 | 3 | 0.12 | 0.15 | 0.22 | 0.29 |
| Ruminant liver | 0.004 | 0.009 | 0.09 | 3 | 0.05 | 0.07 | 0.10 | 0.12 | 0.004 | 0.007 | 0.01\* | 1.7 |
| 0.28 | 3 | 0.15 | 0.16 | 0.25 | 0.28 |
| 0.82 | 3 | 0.46 | 0.60 | 0.75 | 0.96 |
| Ruminant kidney | 0.004 | 0.009 | 0.09 | 3 | 0.02 | 0.03 | 0.04 | 0.06 | 0.002 | 0.003 | 0.01\* | 2.0 |
| 0.28 | 3 | 0.08 | 0.14 | 0.13 | 0.18 |
| 0.82 | 3 | 0.20 | 0.25 | 0.31 | 0.36 |
| Poultry muscle | 0.003 | 0.006 | 0.24 | 3 | <0.01 | <0.01 | <0.01 | <0.01 | 0.0001 | 0.0004 | 0.01\* | 1.0 |
| 0.85 | 3 | <0.01 | 0.02 | 0.01 | 0.02 |
| 2.32 | 3 | 0.03 | 0.05 | 0.03 | 0.06 |
| Poultry fat | 0.003 | 0.006 | 0.24 | 3 | <0.01 | 0.01 | 0.01 | 0.02 | 0.0001 | 0.0004 | 0.01\* | 2.0 |
| 0.85 | 3 | 0.03 | 0.06 | 0.05 | 0.07 |
| 2.32 | 3 | 0.08 | 0.16 | 0.11 | 0.20 |
| Poultry liver | 0.003 | 0.006 | 0.24 | 3 | 0.02 | 0.03 | 0.04 | 0.05 | 0.0004 | 0.001 | 0.01\* | 1.7 |
| 0.85 | 3 | 0.04 | 0.06 | 0.10 | 0.13 |
| 2.32 | 3 | 0.13 | 0.24 | 0.28 | 0.41 |
| Milk(e) | 0.004 | 0.009 | 0.09 | 3 | 0.02 | N/A | 0.04 | N/A | 0.001 | 0.002 | 0.01\* | 2.0 |
| 0.28 | 3 | 0.07 | N/A | 0.12 | N/A |
| 0.82 | 3 | 0.21 | N/A | 0.31 | N/A |
| Eggs | 0.003 | 0.006 | 0.24 | 3 | 0.06 | 0.08 | 0.10 | 0.15 | 0.001 | 0.002 | 0.01\* | 1.9 |
| 0.85 | 3 | 0.12 | 0.17 | 0.21 | 0.32 |
| 2.32 | 3 | 0.58 | 0.80 | 0.91 | 1.44 |

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Based on average dose (mg)/animal weights (kg) i.e. 53.2/602, 168.8/611, 516.3/631 for ruminant; 0.412/1.714, 1.394/1.639, 3.948/1.704 for poultry, during dosing period.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day 1 until day 28 (3 cows, 7 sampling days).

Summary of feeding studies reported in the EU

*Reference: United Kingdom, 2013*

“Two livestock feeding studies were conducted, one in dairy cattle and one in laying hens. In dairy cattle, cyantraniliprole parent was administered to 4 groups of lactating cows twice daily for 28 consecutive days. Dosing was made at target treatment levels of 3, 10, 30 and 100 mg/kg feed based on the animal diet on a dry weight basis. An additional 3 cows were dosed at 100 mg/kg feed to obtain depuration data. In the hen feeding study, cyantraniliprole parent was administered to 3 groups of hens daily for 28 consecutive days. Dosing was made at target treatment levels of 3, 10 and 30 mg/kg feed based on the animal diet on a dry weight basis. An additional group were dosed at 30 mg/kg feed to obtain depuration data.

Overall consistent residue behavior was found in dairy cattle and laying hens for dosing and sampling conducted according to the targeted dosing levels, providing data appropriate for assessing transfer of residues to the animal commodities of milk (raw, skim, cream), eggs, fat, muscle, liver, and kidney”

Conclusion on feeding studies

The addition of maize grain, forage/silage, stover and processed commodities modifies the theoretical maximum daily intake for livestock, but regarding the available feeding data, the calculated MRLs for animal commodities are all < 0.01 mg/kg and there is no risk of animal MRLs being exceeded.

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

Because quantifiable residues of cyantraniliprole are not found in the treated crop and the contribution of maize to the TMDI is <10%, there is no need to investigate the effect of industrial and/or household processing.

#### Available data for all crops under consideration

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

#### Conclusion on processing studies

Because quantifiable residues of cyantraniliprole are not found in the treated crop and the contribution of maize to the TMDI is <10%, there is no need to investigate the effect of industrial and/or household processing.

### 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/have been submitted and are summarized hereafter.

#### Field rotational crop studies (KCA 6.6.2)

Available data

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

Table 7.2‑14: 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 | | | Report reference | Source |
| --- | --- | --- | --- | --- | --- | --- |
| Succeeding crop group | Succeeding crop | Sowing intervals  (DAT) |
| EU reviewed data | | | | | | |
| Bare soil | 0.200 | Leafy vegetables | Spinach | 14, 30, 120, 270 | DuPont-21447 | United Kingdom, 2013 |
| Cereals | Spring barley | 14, 30, 120, 270 |
| Root and tuber vegetables | Radish | 14, 30, 120, 270 |
| Bare soil | 0.45 | Leafy vegetables | Lettuce | 14, 30, 120, 365 | DuPont-19678 | United Kingdom, 2013 |
| Cereals | Spring oats | 14, 30, 120, 365 |
| Root and tuber vegetables | Radish | 14, 30, 120, 365 |
| Pulses/oilseeds | Soybeans | 14, 30, 120, 365 |

Summary of field rotational crop studies

*Reference: United Kingdom, 2013*

“Field rotational crop studies conducted in northern and southern Europe showed that the uptake of cyantraniliprole by rotational crops was very low in all crops studied. All residue levels in the crops were found to be ≤ 0.01 mg/kg cyantraniliprole in commodities for human consumption and 0.05 mg/kg in feed items in any sample from representative crops grown as rotational crops in Europe.”

Conclusion on rotational crops studies

Considering the overdosing factor of the above studies and the fact that cyantraniliprole was applied to a bare soil (interception of cyantraniliprole by the plants is expected in practice), it can be concluded that cyantraniliprole residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that cyantraniliprole is applied in compliance with the GAPs supported for this submission.

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

The available data for cyantraniliprole sufficiently address aspects of the residue situation that might arise from the use of A17960B. Therefore, other special studies are not needed.

### 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).

Because no ARfD was deemed necessary, an acute risk assessment is not required.

#### Input values for the consumer risk assessment

The TMDI calculations for cyantraniliprole using the EFSA PRIMo rev.3.1 model is presented in Table 7.2-16. The highest TMDI for cyantraniliprole is for NL toddler and represents 348% of the ADI. A refined International Estimates of Daily Intake (IEDI) calculation has therefore been conducted. The residue level input values used in these calculations are summarised in the following table.

**Table 7.2‑15: Input values for the consumer risk assessment**

| Code no. | Commodity group or commodity | MRL | Chronic risk assessment | Comments |
| --- | --- | --- | --- | --- |
| STMR (mg/kg) |
| 110010 | Grapefruits | 0.900 | 0.020 | EFSA 2014; 12(9):3814 |
| 110020 | Oranges | 0.900 | 0.020 | EFSA 2014; 12(9):3814 |
| 110030 | Lemons | 0.900 | 0.020 | EFSA 2014; 12(9):3814 |
| 110040 | Limes | 0.900 | 0.020 | EFSA 2014; 12(9):3814 |
| 110050 | Mandarins | 0.900 | 0.020 | EFSA 2014; 12(9):3814 |
| 110990 | Other citrus fruit | 0.900 | 0.020 | EFSA 2014; 12(9):3814 |
| 120010 | Almonds | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120020 | Brazil nuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120030 | Cashew nuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120040 | Chestnuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120050 | Coconuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120060 | Hazelnuts/cobnuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120070 | Macadamia | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120080 | Pecans | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120090 | Pine nut kernels | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120100 | Pistachios | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120110 | Walnuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 120990 | Other tree nuts | 0.040 | 0.010 | EFSA 2016; 14(8):4571 |
| 130010 | Apples | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 130020 | Pears | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 130030 | Quinces | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 130040 | Medlar | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 130050 | Loquats/Japanese medlars | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 130990 | Other pome fruit | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 140010 | Apricots | 0.700 | 0.130 | Evaluation report, France, 2018a |
| 140020 | Cherries (sweet) | 6.000 | 0.930 | EFSA 2014; 12(7):3737 |
| 140030 | Peaches | 1.500 | 0.340 | EFSA 2014; 12(7):3737 |
| 140040 | Plums | 0.700 | 0.120 | EFSA 2014; 12(9):3814 |
| 140990 | Other stone fruit | 1.500 | 0.340 | EFSA 2014; 12(7):3737 |
| 151010 | Table grapes | 1.500 | 0.260 | EFSA 2016; 14(7):4553 |
| 151020 | Wine grapes | 1.500 | 0.580 | EFSA 2016; 14(7):4553 |
| 152000 | Strawberries | 1.500 | 0.455 | EFSA 2019; 17(7):5797 |
| 154010 | Blueberries | 4.000 | 0.750 | EFSA 2014; 12(7):3737 |
| 154020 | Cranberries | 0.08 | 0.012 | EFSA 2019; 17(7):5797 |
| 154030 | Currants (red, black and white) | 4.000 | 0.750 | EFSA 2014; 12(7):3737 |
| 154040 | Gooseberries (green, red and yellow) | 4.000 | 0.750 | EFSA 2014; 12(7):3737 |
| 154050 | Rose hips | 4.000 | 0.750 | EFSA 2014; 12(7):3737 |
| 154070 | Azarole/Mediteranean medlar | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 161030 | Table olives | 3.000 | 0.750 | Evaluation report, France, 2018b |
| 161060 | Kaki/Japanese persimmons | 0.800 | 0.160 | EFSA 2014; 12(7):3737 |
| 163030 | Mangoes | 0.700 | 0.01 | EFSA 2019; 17(7):5797 |
| 211000 | Potatoes | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 212010 | Cassava roots/manioc | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 212020 | Sweet potatoes | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 212030 | Yams | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 212040 | Arrowroots | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 212990 | Other tropical root and tuber vegetables | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213010 | Beetroots | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213020 | Carrots | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213030 | Celeriacs/turnip rooted celeries | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213040 | Horseradishes | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213050 | Jerusalem artichokes | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213060 | Parsnips | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213070 | Parsley roots/Hamburg roots parsley | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213080 | Radishes | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213090 | Salsifies | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213100 | Swedes/rutabagas | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213110 | Turnips | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 213990 | Other other root and tuber vegetables | 0.050 | 0.010 | EFSA 2014; 12(7):3737 |
| 220010 | Garlic | 0.050 | 0.020 | EFSA 2014; 12(7):3737 |
| 220020 | Onions | 0.050 | 0.020 | EFSA 2014; 12(7):3737 |
| 220030 | Shallots | 0.050 | 0.020 | EFSA 2014; 12(7):3737 |
| 220040 | Spring onions/green onions and Welsh onions | 8.000 | 1.300 | EFSA 2014; 12(7):3737 |
| 220990 | Other bulb vegetables | 0.050 | 0.020 | Reg (EU) 2017/626 |
| 231010 | Tomatoes | 1.000 | 0.170 | EFSA 2014; 12(9):3814 |
| 231020 | Sweet peppers/bell peppers | 1.500 | 0.140 | EFSA 2014; 12(9):3814 |
| 231030 | Aubergines/egg plants | 1.000 | 0.140 | EFSA 2014; 12(9):3814 |
| 231040 | Okra/lady’s fingers | 1.500 | 0.140 | EFSA 2014; 12(9):3814 |
| 231990 | Other solanacea | 1.500 | 0.140 | Reg, (EU) 2017/626 |
| 232010 | Cucumbers | 0.400 | 0.080 | EFSA 2014; 12(9):3814 |
| 232020 | Gherkins | 0.400 | 0.080 | EFSA 2014; 12(9):3814 |
| 232030 | Courgettes | 0.400 | 0.080 | EFSA 2014; 12(9):3814 |
| 232990 | Other cucurbits - edible peel | 0.400 | 0.080 | EFSA 2014; 12(9):3814 |
| 233010 | Melons | 0.300 | 0.012 | EFSA 2014; 12(9):3814 |
| 233020 | Pumpkins | 0.300 | 0.002 | EFSA 2014; 12(7):3737 |
| 233030 | Watermelons | 0.300 | 0.002 | EFSA 2014; 12(7):3737 |
| 233990 | Other cucurbits - inedible peel | 0.300 | 0.002 | EFSA 2014; 12(7):3737 |
| 241010 | Broccoli | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 241020 | Cauliflowers | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 241990 | Other flowering brassica | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 242010 | Brussels sprouts | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 242020 | Head cabbages | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 242990 | Other head brassica | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 243010 | Chinese cabbages/pe-tsai | 7.000 | 1.530 | Evaluation report, France, 2018a |
| 243020 | Kales | 7.000 | 1.530 | Evaluation report, France, 2018a |
| 243990 | Other leafy brassica | 7.000 | 1.530 | Evaluation report, France, 2018a |
| 244000 | Kohlrabies | 2.000 | 0.560 | EFSA 2014; 12(7):3737 |
| 251010 | Lamb's lettuce/corn salads | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251020 | Lettuces | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251030 | Escaroles/broad-leaved endives | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251040 | Cress and other sprouts and shoots | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251050 | Land cress | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251060 | Roman rocket/rucola | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251070 | Red mustards | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251080 | Baby leaf crops (including brassica species) | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 251990 | Other lettuce and other salad plants | 15.000 | 4.630 | Evaluation report, France, 2018a |
| 260010 | Beans (with pods) | 1.500 | 0.290 | EFSA 2016; 14(8):4571 |
| 260020 | Beans (without pods) | 0.300 | 0.070 | EFSA 2016; 14(8):4571 |
| 260030 | Peas (with pods) | 2.000 | 0.700 | EFSA 2016; 14(8):4571 |
| 260040 | Peas (without pods) | 0.300 | 0.070 | EFSA 2016; 14(8):4571 |
| 270030 | Celeries | 15.000 | 2.000 | EFSA 2014; 12(7):3737 |
| 270050 | Globe artichokes | 0.100 | 0.030 | EFSA 2015; 13(10):4263 |
| 270060 | Leeks | 0.600 | 0.075 | SANTE/12090/2019 |
| 300010 | Beans | 0.300 | 0.010 | EFSA 2016; 14(8):4571 |
| 401050 | Sunflower seeds | 0.500 | 0.067 | EFSA 2016; 14(8):4571 |
| 401060 | Rapeseeds/canola seeds | 0.800 | 0.077 | EFSA 2016; 14(8):4571 |
| 401070 | Soyabeans | 0.400 | 0.033 | Reg (EU) 2017/626 |
| 401090 | Cotton seeds | 1.500 | 0.160 | EFSA 2016; 14(8):4571 |
| 402010 | Olives for oil production | 3.000 | 0.750 | Evaluation report, France, 2018b |
| 500030 | Maize/corn | 0.01\* | <0.01 | This submission |
| 620000 | Coffee beans | 0.050 | 0.010 | EFSA 2016; 14(8):4571 |
| 633010 | Valerian root | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 633020 | Ginseng root | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 633990 | Other herbal infusions (dried roots) | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 840010 | Liquorice | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 840020 | Ginger | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 840030 | Turmeric/curcuma | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 840040 | Horseradish, root spices | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 840990 | Other spices (roots) | 0.200 | 0.080 | EFSA 2015; 13(10): 4263 |
| 900010 | Sugar beet roots | 0.050 | 0.010 | EFSA 2014; 12(7): 3737 |
| 900030 | Chicory roots | 0.050 | 0.010 | EFSA 2014; 12(7): 3737 |
| Various | Muscle of swine, bovine, sheep, goats, equine, and other farmed terrestrial animals | 0.050 | 0.014 | CF = 1.1  Evaluation report, France, 2018b |
| Various | Fat tissue of swine, bovine, sheep, goats, equine, and other farmed terrestrial animals | 0.010 | 0.004 | CF = 1.8  Evaluation report, France, 2018b |
| Various | Liver of swine, bovine, sheep, goats, equine, and other farmed terrestrial animals | 0.030 | 0.017 | CF = 1.7  Evaluation report, France, 2018b |
| Various | Kidney of swine, bovine, sheep, goats, equine, and other farmed terrestrial animals | 0.015 | 0.007 | CF = 1.6  Evaluation report, France, 2018b |
| Various | Edible offals (other than liver and kidney) of swine, bovine, sheep, goats, equine, and other farmed terrestrial animals | 0.030 | 0.017 | CF = 2.0  Evaluation report, France, 2018b |
| 1020000 | Milk | 0.015 | 0.010 | CF = 2.0  Evaluation report, France, 2018b |
| 1030000 | Birds eggs | 0.010 | 0.002 | CF = 1.7  Evaluation report, France, 2018b |
| 1040000 | Honey | 0.05\* | <0.05 | Regulation (EU) 2017/626 |

\*Denotes an MRL set or proposed at the LOQ

aEvaluation report, France, 2018: an MRL application has been submitted to the RMS and is currently under review: EFSA register of questions number EFSA-Q-2018-00325

bEvaluation report, France, 2018: an MRL application has been submitted to the RMS and is currently under review: EFSA register of questions number EFSA-Q-2018-00324

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2‑16: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 348% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | 81% (based on NL toddler) |
| IESTI (% ARfD) according to EFSA PRIMo\* | Not applicable (no ARfD) |

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

The proposed uses of cyantraniliprole in A17960B do not represent unacceptable chronic risks for the consumer.

## Combined exposure and risk assessment

Not relevant since A17960B contains only a single active substance (cyantraniliprole).

## References

Commission 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. EUR-Lex C/2017/2035, 43 pp.

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole. EFSA Journal 2014;12(9):3814, 249 pp. doi:10.2903/j.efsa.2014.3814.

EFSA (European Food Safety Authority), 2014. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2014;12(7):3737, 182 pp. doi:10.2903/j.efsa.2014.3737.

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the MRLs for cyantraniliprole in various crops. EFSA Journal 2015;13(10):4263, 25 pp. doi:10.2903/j.efsa.2015.4263.

EFSA (European Food Safety Authority), 2016. Scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2016;12(8):4571, 166 pp. doi: 10.2903/j.efsa.2016.4571.

EFSA (European Food Safety Authority), 2016. Reasoned opinion on the modification of the existing maximum residue level for cyantraniliprole in table grapes. EFSA Journal 2016;14(7):4553, 14 pp. doi:10.2903/j.efsa.2016.4553.

FAO (Food and Agriculture Organization of the United Nations), 2015. cyantraniliprole. In: Pesticide residues in food – 2015. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 223.

France, 2018. Evaluation Report Prepared under Article 8 of Regulation (EC) No 396/2005. Setting of MRLs for cyantraniliprole in olives, February 2018. EFSA Register of Questions number EFSA-Q-2018-00324.

France, 2018. Evaluation Report Prepared under Article 8 of Regulation (EC) No 396/2005. Evaluation Report on MRLs for cyantraniliprole in peaches, apricots, onions, garlic, shallots, leafy brassica, lettuce and other salads, beans (fresh, with pods), leek and commodities of animal origin, June 2018. EFSA Register of Questions number EFSA-Q-2018-0032~~4~~5.

France 2018. Setting of MRLs for cyantraniliprole in peaches, apricots, onions, garlic, shallots, leafy brassica, lettuce and other salads, beans (fresh, with pods), leek and commodities of animal origin.

UK, 2013. Draft assessment report on the active substance cyantraniliprole prepared by the rapporteur Member State United Kingdom and co-RMS France in the framework of Regulation (EC) No.1107/2009, May 2013

UK, 2014. Final Addendum to the draft assessment report on the active substance cyantraniliprole prepared by the rapporteur Member State United Kingdom and co-rapporteur Member State France in the framework of Regulation (EC) No.1107/2009, September 2014.

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 |
| --- | --- | --- | --- | --- | --- |
| KCA 6.3 | Andrews, G. | 21/08/2014 | Cyantraniliprole- Residue Study, Following Seed Treatment, on Maize in Southern France in 2012 Report No. TK0114206 Document No. VV-409538 , A17960B\_10072 Test Facility Battelle UK Ltd GLP Unpublished | N | SYN/ FMC # |
| KCA 6.3 | Andrews, G. | 01/04/2015 | Cyantraniliprole – Residue Study, Following Seed Treatment, on Maize in Southern France in 2014 Report No. NC14018 Document No. VV-413962 , A17960B\_10263 Test Facility Battelle UK Ltd GLP Unpublished | N | SYN |
| KCA 6.3 | Campbell, D. Doig, A. | 22/07/2014 | Magnitude and Decline of Cyantraniliprole (DPX-HGW86) and Metabolite Residues in Commodities Derived from Maize Grown from Seed Treated with Cyantraniliprole - EU - 2013 Initiation Report No. DuPont-37524|698157 Document No. VV-471608 , SYN545377\_12310 Test Facility Charles River Laboratories GLP Unpublished | N | SYN |

# Syngenta co-own study with FMC (In Nov 2017 DuPont divested cyantraniliprole to FMC)

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 | Carol A. Rodgers | 2010 | STABILITY OF DPX-HGW86 AND METABOLITE/DEGRADATION PRODUCT RESIDUES IN REPRESENTATIVE CROPS STORED FROZEN  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-16990  ABC Laboratories, Inc. 7200 East ABC Lane Columbia, Missouri 65202, Inc.: 63450  GLP  not published  Syngenta File No VV-394587 | N | DuPont |
| KCA 6.1 | Sian Roberts,  Clive Ward | 2010 | MAGNITUDE OF RESIDUES OF CYANTRANILIPROLE (DPX-HGW86) AND METABOLITES IN EDIBLE TISSUES AND EGGS OF POULTRY FOLLOWING DOSING WITH CYANTRANILIPROLE  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-27181  Charles River Tranent Edinburgh EH33 2NE UK  Charles River Project Number: 285816  Charles River Report Number: 30558  GLP  not published  Syngenta File No VV-394450 | Y | DuPont |
| KCA 6.1 | Clive Ward, Ciara Vance, | 2011 | DPX-HGW86: MAGNITUDE OF RESIDUES OF CYANTRANILIPROLE (DPX-HGW86) AND IT’S METABOLITES IN EDIBLE TISSUES AND MILK OF LACTATING DIARY COWS FOLLOWING DOSING WITH CYANTRANILIPROLE  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-27180, Revision 1  Charles River Tranent Edinburgh EH33 2NE UK  Charles River Report Number: 215492  GLP  not published  Syngenta File No VV-866714 | Y | DuPont |
| KCA 6.2.1 | I MacKinnon | 2008 | THE METABOLISM OF [ 14C]DPX-HGW86 IN TOMATOES  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: Dupont-16985  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806185  GLP  not published  Syngenta File No VV-382855 | N | DuPont |
| KCA 6.2.1 | I MacKinnon | 2008 | THE METABOLISM OF [ 14C]DPX-HGW86 IN LETTUCE  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-16986  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806190  GLP  not published  Syngenta File No VV-382982 | N | DuPont |
| KCA 6.2.1 | A M G MacDonald MacKinnon  S Chapleo | 2008 | THE METABOLISM OF [ 14C]DPX-HGW86 IN COTTON  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: Dupont-16984, Rev 1  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806143  GLP  not published  Syngenta File No VV-382601 | N | DuPont |
| KCA 6.2.1 | S Chapleo,  G Hobbs,  A M G Grant-MacDonald | 2010 | THE METABOLISM OF [ 14C]DPX-HGW86 (CYANTRANILPROLE) IN RICE  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-18780  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 808470  GLP  not published  Syngenta File No VV-393490 | N | DuPont |
| KCA 6.6.1 | Martin T. Scott R. Scott Swain Gonzelous A. Young | 2006 | [ 14C]DPX-HGW86 PILOT CONFINED CROP ROTATION STUDY (WHEAT, SOYBEANS, AND RED BEETS)  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-15513  E. I. du Pont de Nemours and Company DuPont Crop Protection Global Technology Division Stine-Haskell Research Center Newark, Delaware 19714-0030 USA  GLP  not published  Syngenta File No VV-382460 | N | DuPont |
| KCA 6.6.1 | S. Chapleo,  M. A. Green | 2009 | CONFINED ROTATIONAL CROP STUDY USING [ 14C]DPX-HGW86  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-15778  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806248  GLP  not published  Syngenta File No VV-395620 | N | DuPont |
| KCA 6.5.1 | Chris Lowrie | 2005 | HIGH TEMPERATURE HYDROLYSIS OF [ 14C]-DPX-HGW86 IN BUFFERED AQUEOUS SOLUTION AT PH 4, 5, AND 6  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: Dupont-16989  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806321  GLP  not published  Syngenta File No VV-382603 | N | DuPont |
| KCA 6.2.2-6.2.5 | Graeme McLellan, Ciara Vance,  Chris Lowrie | 2008 | METABOLISM OF [14C]DPX-HGW86 IN THE LACTATING GOAT  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: Dupont-16987  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806122  GLP  not published  Syngenta File No VV-383107 | Y | DuPont |
| KCA 6.2.2-6.2.5 | Graeme McLellan,  Chris Lowrie | 2008 | THE METABOLISM OF [14C]DPX-HGW86 IN THE LAYING HEN  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: Dupont-16988  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 806227  GLP  not published  Syngenta File No VV-383108 | Y | DuPont |
| KCA 6.6.2 | Ian Haigh  Laura Woodmansey | 2010 | MAGNITUDE AND DECLINE OF DPX-HGW86 AND METABOLITE AND/OR DEGRADATION PRODUCT RESIDUES IN FIELD ROTATIONAL CROPS FOLLOWING FOLIAR APPLICATION OF DPX-HGW86 100G/L OD- NORTHEN EUROPE 2008 AND 2009  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-21447  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 693630  GLP  not published  Syngenta File No VV-400946 | N | DuPont |
| KCA 6.6.2 | Jeff Old  Laura Woodmansey | 2010 | FIELD CROP ROTATION STUDY WITH DPX-HGW86 INSECTICIDE - SOUTHERN EUROPE 2006 - 2009  E. I. du Pont de Nemours and Company Wilmington, Delaware 19898 U.S.A.  DuPont Study Number: DuPont-19678  Charles River Laboratories Tranent Scotland EH22 3NE  Charles River Laboratories Project Number: 690378  GLP  not published  Syngenta File No VV-401027 | N | DuPont |

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 |
| --- | --- | --- | --- | --- | --- |
| - | - | - | - | - | - |

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 |
| --- | --- | --- | --- | --- | --- |
| - | - | - | - | - | - |

1. Detailed evaluation of the additional studies relied upon
   1. Cyantraniliprole
      1. Stability of residues

No new data are submitted.

* + 1. Nature of residues in plants, livestock and processed commodities

No new data are submitted.

* + 1. Magnitude of residues in plants
       1. Maize

Table A 1: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applica­tions | Application rate per treatment  (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP EU (DAR) | - | - | - | - | - |
| cGAP EU (Art. 12, EFSA, year) | - | - | - | - | - |
| **Interzonal cGAP A17960B** | **1** | **450 µg as/seed** | **N/A** | **BBCH 00** | **N/A** |
| Intended cGAP (1,2,3\*) | 1 | 450 µg as/seed | N/A | BBCH 00 | N/A |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

N/A: not applicable

* + - * 1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | The study included ten supervised residue trials conducted in North (5 trials) and South (5 trials) Europe during the 2013 season to determine the magnitude of cyantraniliprole (DPX-HGW86) and metabolite residues in commodities derived from maize in Europe grown from seeds treated with cyantraniliprole. Cyantraniliprole 625 g/L FS was applied to maize seeds at a target rate of 750 μg as/seed.  An analytical method used: based on DuPont-15736 with adaptations by Charles River (Analytical Method No. 1187A).  Specimens were analysed by LC-MS/MS for residues of DPX-HGW86 and metabolites (IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98 and, IN-N7B69. The determined Limit of Quantification (LOQ) was 0.010 mg/kg. The Limit of Detection (LOD) was 0.003 mg/kg. Concurrent recoveries for all analytes from untreated samples of all matrices (whole plant, cobs, grain and stover) fortified at the LOQ (0.010 mg/kg) and the 10 x LOQ (0.10 mg/kg) ranged from 60-110%.  Residues of cyantraniliprole and metabolites found in treated whole plant samples collected at BBCH 75-81/82, cobs collected at BBCH 83-85 and mature grain and stover collected at commercial harvest, following one application of Cyantraniliprole 625 g/L FS formulated product to dry seed are summarized in the following table.    Treated samples for this study were stored at ca -18°C for less than 7 months between sampling and analysis. The study on the magnitude of residues is valid with regard to storage stability.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Magnitude and Decline of Cyantraniliprole (DPX-HGW86) and Metabolite Residues in Commodities Derived from Maize Grown from Seed Treated with Cyantraniliprole – EU – 2013 Initiation.  Doig A, Campbell D, 2014  Report No. DuPont-37524 Syngenta File No VV-471608 |
| Guideline(s): | OECD Test Guideline 508, OECD Guideline for the Testing of Chemicals: Magnitude of the Pesticide Residues in Processed Commodities, 03 October 2008  OECD Test Guideline 509, OECD Guideline for the Testing of Chemicals: Crop Field Trial, 07 September 2009  European Communities Guidelines for the Generation of Data Concerning Residues, as Provided in Annex II, Part A, Section 6 and Annex III, Part A, Section 8 of EC Commission Directive 91/414/EEC.  SANCO/825/00 rev.8.1 (16/11/2010) Guidance Document on Pesticide Residue Analytical Methods |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 2: Summary of the study 1 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Field Trials, Crop Residue (Summary): Magnitude and Decline of Cyantraniliprole (DPX-HGW86) and Metabolite Residues in Commodities Derived from Maize Grown from Seed Treated with Cyantraniliprole – EU – 2013 Initiation | | | |
| Active Substance (common name): | Cyantraniliprole | Commercial Product (name): | DPX-HGW86-750 |
| Crop/Crop Group: | Maize / Cereal | Producer of commercial product: | E. I. du Pont de Nemours and Company |
| Responsible body for reporting (name, address): | DuPont Crop Protection, E. I. du Pont de Nemours and Company, Wilmington, Delaware 19898, U.S.A. | Indoor/Glasshouse/Outdoor: | Field |
| Country: | France, The Netherlands, Germany, Austria, Hungary, Spain, Italy | Other active substance in the formulation (common name and content): | None |
| Content of active substance (g/kg or g/L): | 625 g a.s./L | Residues calculated as: | Cyantraniliprole (DPX-HGW86; mg/kg) |
| Formulation (e.g. WP): | FS |  |  |
| Analytical Method: Cyantraniliprole (Whole plants, cobs plus kernels, grain and stover): DuPont-15736 (Charles River Analytical Method No. 1187A); 0.01 mg/kg | | | |
| Recovery data: Cyantraniliprole: Whole plant Mean = 91% RSD = 6.3% (n = 6 in 0.01 - 0.1 mg/kg spiking range) Cyantraniliprole: Cobs plus kernels Mean = 80% RSD = 9.9% (n = 6 in 0.01 - 0.1 mg/kg spiking range) Cyantraniliprole: Mature grain Mean = 68% RSD = 17% (n = 6 in 0.01 - 0.1 mg/kg spiking range) Cyantraniliprole: Stover Mean = 85% RSD = 10% (n = 6 in 0.01 - 0.1 mg/kg spiking range) | | | |

| (1) Report No. Trial No. Location (Region) (Postcode) | (2) Commodity/ Variety (a) | (3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b) | (4) Method of Treatment | (5) Application rate per treatment | | | (6) Planting Date  (c) | (7) Growth Stage at Treatment | (8) Portion Analysed | (9) Residue found (Uncorrected) | (10) PHI (d) | (11) Sample Date (Cut Date) (d) | (12) Trial Details (e) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Conc'n | Water | Rate (Additive Type, Rate) | Cyantraniliprole (mg/kg) |
| DuPont-37524 Test 01 Douai, 59500 Nord-Pas de Calais, France (North) NEU | Maize/ Pioneer Hybrid P8000 | 1. 27 May 2013 2. NR 3. 14 Nov 2013 | - | - | - | -  (-) | 27 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 119 | 23 Sep 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 140 | 14 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 171 | 14 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 171 | 14 Nov 2013 |
| Seed | n/a | n/a | 846 µg/seed  (-) | 27 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 119 | 23 Sep 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 126 | 30 Sep 2013 |
| BBCH 00 | Cobs | < 0.01 | 140 | 14 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 171 | 14 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 171 | 14 Nov 2013 |
| DuPont-37524 Test 02 6599 AV Ven-Zelderheide, Limburg, The Netherlands NEU | Maize/ Pioneer Hybrid P8000 | 1. 07 May 2013 2. NR 3. 10 Dec 2013 | - | - | - | -  (-) | 07 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 134 | 18 Sep 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 153 | 07 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 217 | 10 Dec 2013 |
| BBCH 00 | Stover | < 0.01 | 217 | 10 Dec 2013 |
| Seed | n/a | n/a | 846 µg/seed  (-) | 07 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 134 | 18 Sep 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 141 | 25 Sep 2013 |
| BBCH 00 | Cobs | < 0.01 | 153 | 07 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 217 | 10 Dec 2013 |
| BBCH 00 | Stover | < 0.01 | 217 | 10 Dec 2013 |
| DuPont-37524 Test 03 Motterwitz, 04668, Leipzig, Germany NEU | Maize/ Pioneer Hybrid P8000 | 1. 06 May 2013 2. NR 3. 30 Oct 2013 | - | - | - | -  (-) | 06 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 121 | 04 Sep 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 134 | 17 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 177 | 30 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 177 | 30 Oct 2013 |
| Seed | n/a | n/a | 846 µg/seed  (-) | 06 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 121 | 04 Sep 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 128 | 11 Sep 2013 |
| BBCH 00 | Cobs | < 0.01 | 134 | 17 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 177 | 30 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 177 | 30 Oct 2013 |
| DuPont-37524 Test 04 Rohrau 2471, Burgenland, Austria NEU | Maize/ P9400 | 1. 13 May 2013 2. NR 3. 08 Oct 2013 | - | - | - | -  (-) | 13 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 92 | 13 Aug 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 114 | 04 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 148 | 08 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 148 | 08 Oct 2013 |
| Seed | n/a | n/a | 925 µg/seed  (-) | 13 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 92 | 13 Aug 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 99 | 20 Aug 2013 |
| BBCH 00 | Cobs | < 0.01 | 114 | 04 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 148 | 08 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 148 | 08 Oct 2013 |
| DuPont-37524 Test 05 Monsonmagyaróvár, 9200, Gyõr-Moson-Sopron, Hungary NEU | Maize/ P9400 | 1. 10 May 2013 2. NR 3. 10 Oct 2013 | - | - | - | -  (-) | 10 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 102 | 20 Aug 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 116 | 03 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 153 | 10 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 153 | 10 Oct 2013 |
| Seed | n/a | n/a | 925 µg/seed  (-) | 10 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 102 | 20 Aug 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 109 | 27 Aug 2013 |
| BBCH 00 | Cobs | < 0.01 | 116 | 03 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 153 | 10 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 153 | 10 Oct 2013 |
| DuPont-37524 Test 06 Alpicat, 25110, Catalunya, Spain SEU | Maize/ P31D58 | 1. 30 May 2013 2. NR 3. 06 Nov 2013 | - | - | - | -  (-) | 30 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 84 | 22 Aug 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 99 | 06 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 160 | 06 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 160 | 06 Nov 2013 |
| Seed | n/a | n/a | 771 µg/seed  (-) | 30 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 84 | 22 Aug 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 91 | 29 Aug 2013 |
| BBCH 00 | Cobs | < 0.01 | 99 | 06 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 160 | 06 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 160 | 06 Nov 2013 |
| DuPont-37524 Test 07 Utrera, 41710,  Andalucia, Spain SEU | Maize/ P31D58 | 1. 02 May 2013 2. NR 3. 26 Sep 2013 | - | - | - | -  (-) | 02 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 83 | 24 Jul 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 98 | 08 Aug 2013 |
| BBCH 00 | Grain | < 0.01 | 147 | 26 Sep 2013 |
| BBCH 00 | Stover | < 0.01 | 147 | 26 Sep 2013 |
| Seed | n/a | n/a | 771 µg/seed  (-) | 02 May 2013 | BBCH 00 | Whole Plant | < 0.01 | 83 | 24 Jul 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 90 | 31 Jul 2013 |
| BBCH 00 | Cobs | < 0.01 | 98 | 08 Aug 2013 |
| BBCH 00 | Grain | < 0.01 | 147 | 26 Sep 2013 |
| BBCH 00 | Stover | < 0.01 | 147 | 26 Sep 2013 |
| DuPont-37524 Test 08 Saint-Trivier sur Moignans, 01990, Rhône-Alpes, France SEU | Maize/ P0725 | 1. 24 Apr 2013 2. NR 3. 23 Oct 2013 | - | - | - | -  (-) | 24 Apr 2013 | BBCH 00 | Whole Plant | < 0.01 | 126 | 28 Aug 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 150 | 21 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 182 | 23 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 182 | 23 Oct 2013 |
| Seed | n/a | n/a | 838 µg/seed  (-) | 24 Apr 2013 | BBCH 00 | Whole Plant | < 0.01 | 126 | 28 Aug 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 133 | 04 Sep 2013 |
| BBCH 00 | Cobs | < 0.01 | 150 | 21 Sep 2013 |
| BBCH 00 | Grain | < 0.01 | 182 | 23 Oct 2013 |
| BBCH 00 | Stover | < 0.01 | 182 | 23 Oct 2013 |
| DuPont-37524 Test 09 Graffignana 26813, Lombardia, Italy SEU | Maize/ P31A34 | 1. 05 Jun 2013 2. NR 3. 06 Nov 2013 | - | - | - | -  (-) | 05 Jun 2013 | BBCH 00 | Whole Plant | < 0.01 | 104 | 17 Sep 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 127 | 10 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 154 | 06 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 154 | 06 Nov 2013 |
| Seed | n/a | n/a | 850 µg/seed  (-) | 05 Jun 2013 | BBCH 00 | Whole Plant | < 0.01 | 104 | 17 Sep 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 111 | 24 Sep 2013 |
| BBCH 00 | Cobs | < 0.01 | 127 | 10 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 154 | 06 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 154 | 06 Nov 2013 |
| DuPont-37524 Test 10 Cervesina, 27050, Lombardia, Italy SEU | Maize/ P31A34 | 1. 04 Jun 2013 2. NR 3. 07 Nov 2013 | - | - | - | -  (-) | 04 Jun 2013 | BBCH 00 | Whole Plant | < 0.01 | 104 | 16 Sep 2013 | Field  SP (max days): Cyantraniliprole/ 7 Months |
| BBCH 00 | Cobs | < 0.01 | 127 | 09 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 156 | 07 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 156 | 07 Nov 2013 |
| Seed | n/a | n/a | 850 µg/seed  (-) | 04 Jun 2013 | BBCH 00 | Whole Plant | < 0.01 | 104 | 16 Sep 2013 |
| BBCH 00 | Whole Plant | < 0.01 | 111 | 23 Sep 2013 |
| BBCH 00 | Cobs | < 0.01 | 127 | 09 Oct 2013 |
| BBCH 00 | Grain | < 0.01 | 156 | 07 Nov 2013 |
| BBCH 00 | Stover | < 0.01 | 156 | 07 Nov 2013 |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP = storage period; NR = not recorded; n/a = not applicable

* + - * 1. Study 2

|  |  |  |
| --- | --- | --- |
| Comments of zRMS: | Three decline residue field trials on maize were successfully conducted in southern France during 2012. Cyantraniliprole (SYN545377) was applied as a seed treatment at a rate of 0.6 mg cyantraniliprole / seed using A17960B, a flowable concentrate for seed treatment (FS) formulation containing 600 g cyantraniliprole / L.  For trials S12-01322-01, S12-01322-02 and S12-01322-03, treated maize samples were collected as whole plant at BBCH 39, 63 and 83-85 and whole cobs and remaining plant at BBCH 75-79 and 89. Samples were analysed for cyantraniliprole (SYN545377) and its metabolites, IN-N7B69 (M1), IN-JCZ38 (M2), IN-K5A79 (M3), IN-MYX98 (M4), IN-MLA84 (M5), IN-J9Z38 (M6) and IN-K7H19 (M7).  An analytical method used: DuPont-15736.  Specimens were analysed by LC-MS/MS for residues of DPX-HGW86 and metabolites (IN-N7B69 (M1), IN-JCZ38 (M2), IN-K5A79 (M3), IN-MYX98 (M4), IN-MLA84 (M5), IN-J9Z38 (M6) and IN-K7H19 (M7)). The determined Limit of Quantification (LOQ) was 0.010 mg/kg. The Limit of Detection (LOD) was 0.003 mg/kg. Procedural recoveries for all analytes from untreated samples of all matrices (cobs, kernels, remaining plant and whole plant ) fortified at the LOQ (0.010 mg/kg) and the 10 x LOQ (0.10 mg/kg) ranged from 70-110%.  Residues of cyantraniliprole in maize whole plant samples taken at BBCH 39, BBCH 63 and BBCH 83-85, in maize whole cob samples taken at BBCH 75-79 and BBCH 89, in maize remaining plant samples taken at BBCH 75-79 and BBCH 89b were below the limit of quantification (0.01 mg/kg).  Residues of cyantraniliprole metabolites IN-N7B69, IN-JCZ38, IN-K5A79, IN-MYX98, IN-MLA84, IN-J9Z38 and IN-K7H19 in maize whole plant samples taken at BBCH 39, BBCH 63 and BBCH 83-85, in maize whole cob samples taken at BBCH 75-79 and BBCH 89, in maize remaining plant samples taken at BBCH 75-79 and BBCH 89 were all below the limit of quantification (0.01 mg/kg).  Specimens were stored frozen for a maximum period of 182 days (approx. 6 months) from sampling to analysis. The study on the magnitude of residues is valid with regard to storage stability.  The study is acceptable.  Remark:  The both trials: S12-01322-02 and S12-01322-03 were conducted in France, in Tarn et Garonne. However, the distance between locations of plots was above 30 km. It is acceptable to consider that the trials are independent. | |
| Reference: | | KCA 6.3 |
| Report | | Cyantraniliprole– Residue Study, Following Seed Treatment, on Maize in Southern France in 2012.  Andrews G, 2014  Report No. TK0114206 Syngenta File No VV-409538 |
| Guideline(s): | | Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).  Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.  European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).  European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010). |
| Deviations: | | No |
| GLP: | | Yes |
| Acceptability: | | Yes |

Table A 3: Summary of the study 2 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Field Trials, Crop Residue (Summary) : Cyantraniliprole– Residue Study, Following Seed Treatment, on Maize in Southern France in 2012 | | | |
| Active Substance (common name): | Cyantraniliprole | Commercial Product (name): | A17960B |
| Crop/Crop Group: | Maize / Cereal | Producer of commercial product: | Syngenta |
| Responsible body for reporting (name, address): | Syngenta Ltd., Jealott’s Hill International Research Centre, Bracknell, Berkshire, RG42 6EY,United Kingdom | Indoor/Glasshouse/Outdoor: | Field |
| Country: | France | Other active substance in the formulation (common name and content): | None |
| Content of active substance (g/kg or g/L): | 600 g a.s./L | Residues calculated as: | Cyantraniliprole (mg/kg) |
| Formulation (e.g. WP): | FS |  |  |
| Analytical Method: Cyantraniliprole (Whole plants, cobs plus kernels, remaining plants): DuPont-15736; 0.01 mg/kg | | | |
| Recovery data: Cyantraniliprole: Whole plant Mean = 77% RSD = 5.7% (n = 7 in 0.01 - 0.1 mg/kg spiking range) – including remaining plant Cyantraniliprole: Cobs plus kernels Mean = 93% RSD = 5.6% (n = 6 in 0.01 - 0.1 mg/kg spiking range) | | | |

| (1) Report No. Trial No. Location (Region) (Postcode) | (2) Commodity/ Variety (a) | (3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b) | (4) Method of Treatment | (5) Application rate per treatment | | | (6) Planting Date  (c) | (7) Growth Stage at Treatment | (8) Portion Analysed | (9) Residue found (Uncorrected) | (10) PHI (d) | (11) Sample Date (Cut Date) (d) | (12) Trial Details (e) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Conc'n | Water | Rate (Additive Type, Rate) | Cyantraniliprole (mg/kg) |
| TK0114206 S12-01322-01 Saint-Cyprien 66750, Pyrénées-Orientales, France (South) SEU | Maize/ CA4081A CISCO | 1. 19 Jun 2012 2. NR 3. 08 Oct 2012 | - | - | - | -  (-) | 19 Jun 2012 | BBCH 00 | Cobs | < 0.01 | 86 | 13 Sep 2012 | Field  SP (max days): Cyantraniliprole/ 182 Days (6 Months) |
| BBCH 00 | Whole Plant | < 0.01 | 100 | 27 Sep 2012 |
| BBCH 00 | Cobs | < 0.01 | 105 | 02 Oct 2012 |
| BBCH 00 | Remaining Plant | < 0.01 | 105 | 02 Oct 2012 |
| Seed | n/a | n/a | 584 µg/seed  (-) | 19 Jun 2012 | BBCH 00 | Whole Plant | < 0.01 | 51 | 09 Aug 2012 |
| BBCH 00 | Whole Plant | < 0.01 | 63 | 21 Aug 2012 |
| BBCH 00 | Cobs | < 0.01 | 86 | 13 Sep 2012 |
| BBCH 00 | Remaining plant | < 0.01 | 86 | 13 Sep 2012 |
| BBCH 00 | Whole plant | < 0.01 | 100 | 27 Sep 2012 |
| BBCH 00 | Cobs | < 0.01 | 105 | 02 Oct 2012 |
| BBCH 00 | Remaining plant | < 0.01 | 105 | 02 Oct 2012 |
| TK0114206 S12-01322-02 Meauzac 82290, Tarn et Garonne, France (South) SEU | Maize/ CA4081A CISCO | 1. 29 May 2012 2. NR 3. 22 Oct 2012 | - | - | - | -  (-) | 29 May 2012 | BBCH 00 | Cobs | < 0.01 | 100 | 06 Sep 2012 | Field  SP (max days): Cyantraniliprole/ 182 Days (6 Months) |
| BBCH 00 | Whole Plant | < 0.01 | 114 | 20 Sep 2012 |
| BBCH 00 | Cobs | < 0.01 | 146 | 22 Oct 2012 |
| BBCH 00 | Remaining Plant | < 0.01 | 146 | 22 Oct 2012 |
| Seed | n/a | n/a | 584 µg/seed  (-) | 29 May 2012 | BBCH 00 | Whole Plant | < 0.01 | 55 | 23 Jul 2012 |
| BBCH 00 | Whole Plant | < 0.01 | 70 | 07 Aug 2012 |
| BBCH 00 | Cobs | < 0.01 | 100 | 06 Sep 2012 |
| BBCH 00 | Remaining plant | < 0.01 | 100 | 06 Sep 2012 |
| BBCH 00 | Whole plant | < 0.01 | 114 | 20 Sep 2012 |
| BBCH 00 | Cobs | < 0.01 | 146 | 22 Oct 2012 |
| BBCH 00 | Remaining plant | < 0.01 | 146 | 22 Oct 2012 |
| TK0114206 S12-01322-03 Le Pin 82340, Tarn et Garonne, France (South) SEU | Maize/ CA4081A CISCO | 1. 09 Jul 2012 2. NR 3. 12 Nov 2012 | - | - | - | -  (-) | 09 Jul 2012 | BBCH 00 | Cobs | < 0.01 | 81 | 28 Sep 2012 | Field  SP (max days): Cyantraniliprole/ 182 Days (6 Months) |
| BBCH 00 | Whole Plant | < 0.01 | 88 | 05 Oct 2012 |
| BBCH 00 | Cobs | < 0.01 | 126 | 12 Nov 2012 |
| BBCH 00 | Remaining Plant | < 0.01 | 126 | 12 Nov 2012 |
| Seed | n/a | n/a | 584 µg/seed  (-) | 09 Jul 2012 | BBCH 00 | Whole Plant | < 0.01 | 36 | 14 Aug 2012 |
| BBCH 00 | Whole Plant | < 0.01 | 59 | 06 Sep 2012 |
| BBCH 00 | Cobs | < 0.01 | 81 | 28 Sep 2012 |
| BBCH 00 | Remaining plant | < 0.01 | 81 | 28 Sep 2012 |
| BBCH 00 | Whole plant | < 0.01 | 88 | 05 Oct 2012 |
| BBCH 00 | Cobs | < 0.01 | 126 | 12 Nov 2012 |
| BBCH 00 | Remaining plant | < 0.01 | 126 | 12 Nov 2012 |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP = storage period

NR = not recorded

n/a = not applicable

* + - * 1. Study 3

|  |  |  |
| --- | --- | --- |
| Comments of zRMS: | One decline residue field trial on maize was successfully conducted in southern France during 2014. Cyantraniliprole (SYN545377) was applied as a seed treatment at a rate of 0.6 mg cyantraniliprole / seed using A17960B, a flowable concentrate for seed treatment (FS) formulation containing 600 g cyantraniliprole / L.  For trial S14-01644-01 treated maize samples were collected as whole plant at BBCH 39, 63 and 83-85 and whole cobs and remaining plant at BBCH 75-79 and 89. Untreated samples for whole plant were collected at BBCH 83-85, whole cobs at BBCH 75-79 and 89 and remaining plant at BBCH 89.  An analytical method used: DuPont-15736.  Specimens were analysed by LC-MS/MS for residues of DPX-HGW86 and metabolites (IN-N7B69 (M1), IN-JCZ38 (M2), IN-K5A79 (M3), IN-MYX98 (M4), IN-MLA84 (M5), IN-J9Z38 (M6) and IN-K7H19 (M7)). The determined Limit of Quantification (LOQ) was 0.010 mg/kg. The Limit of Detection (LOD) was 0.003 mg/kg. Procedural recoveries for all analytes from untreated samples of all matrices (cobs, kernels, remaining plant and whole plant ) fortified at the LOQ (0.010 mg/kg) and the 10 x LOQ (0.10 mg/kg) ranged from 60-110%.  Residues of cyantraniliprole in maize whole plant samples taken at BBCH 39, BBCH 63 and BBCH 83-85, in maize whole cob samples taken at BBCH 75-79 and BBCH 89 and in maize remaining plant samples taken at BBCH 75-79 and BBCH 89 were below the limit of quantification (0.01 mg/kg).  Residues of cyantraniliprole metabolites IN-N7B69, IN-JCZ38, IN-K5A79, IN-MYX98, IN-MLA84, IN-J9Z38 and IN-K7H19 in maize whole plant samples taken at BBCH 39, BBCH 63 and BBCH 83-85, in maize whole cob samples taken at BBCH 75-79 and BBCH 89 and in maize remaining plant samples taken at BBCH 75-79 and BBCH 89 were all below the limit of quantification (0.01 mg/kg).  Specimens were stored frozen for a maximum period of 164 days (approx. 6 months) from sampling to analysis. The study on the magnitude of residues is valid with regard to storage stability.  The study is acceptable. | |
| Reference: | | KCA 6.3 |
| Report | | Cyantraniliprole – Residue Study, Following Seed Treatment, on Maize in Southern France in 2014.  Andrews G, 2015  Report No. NC14018 Syngenta File No VV-413962 |
| Guideline(s): | | Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).  Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.  European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).  European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010). |
| Deviations: | | No |
| GLP: | | Yes |
| Acceptability: | | Yes |

Table A 4: Summary of the study 3 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Field Trials, Crop Residue (Summary) : Cyantraniliprole – Residue Study, Following Seed Treatment, on Maize in Southern France in 2014 | | | |
| Active Substance (common name): | Cyantraniliprole | Commercial Product (name): | A17960B |
| Crop/Crop Group: | Maize / Cereal | Producer of commercial product: | Syngenta |
| Responsible body for reporting (name, address): | Syngenta Ltd., Jealott’s Hill International Research Centre, Bracknell, Berkshire, RG42 6EY,United Kingdom | Indoor/Glasshouse/Outdoor: | Field |
| Country: | France | Other active substance in the formulation (common name and content): | None |
| Content of active substance (g/kg or g/L): | 600 g a.s./L | Residues calculated as: | Cyantraniliprole (mg/kg) |
| Formulation (e.g. WP): | FS |  |  |
| Analytical Method: Cyantraniliprole (Whole plants, cobs, kernels, remaining plants): DuPont-15736; 0.01 mg/kg | | | |
| Recovery data: Cyantraniliprole: Whole plant Mean = 80% RSD = n/a (n = 2 in 0.01 - 0.1 mg/kg spiking range) Cyantraniliprole: Cobs Mean = 78% RSD = n/a (n = 2 in 0.01 - 0.1 mg/kg spiking range) Cyantraniliprole: Kernels Mean = 95% RSD = n/a (n = 2 in 0.01 - 0.1 mg/kg spiking range) Cyantraniliprole: Remaining plants Mean = 76% RSD = n/a (n = 2 in 0.01 - 0.1 mg/kg spiking range) | | | |

| (1) Report No. Trial No. Location (Region) (Postcode) | (2) Commodity/ Variety (a) | (3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b) | (4) Method of Treatment | (5) Application rate per treatment | | | (6) Planting Date  (c) | (7) Growth Stage at Treatment | (8) Portion Analysed | (9) Residue found (Uncorrected) | (10) PHI (d) | (11) Sample Date (Cut Date) (d) | (12) Trial Details (e) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Conc'n | Water | Rate (Additive Type, Rate) | Cyantraniliprole (mg/kg) |
| NC14018 S14-01644-01 Meauzac 82290, Tarn et Garonne, France (South) SEU | Maize/ Timic 6004 | 1. 03 Jun 2014 2. NR 3. 07 Nov 2014 | - | - | - | -  (-) | 03 Jun 2014 | BBCH 00 | Cobs | < 0.01 | 105 | 16 Sep 2014 | Field  SP (max days): Cyantraniliprole/ 164 Days (6 Months) |
| BBCH 00 | Kernels | < 0.01 | 105 | 16 Sep 2014 |
| BBCH 00 | Whole cobs | < 0.01 | 105 | 16 Sep 2014 |
| BBCH 00 | Whole plants | < 0.01 | 132 | 13 Oct 2014 |
| BBCH 00 | Cobs | < 0.01 | 157 | 07 Nov 2014 |
| BBCH 00 | Kernels | < 0.01 | 157 | 07 Nov 2014 |
| BBCH 00 | Whole cobs | < 0.01 | 157 | 07 Nov 2014 |
| BBCH 00 | Remaining plants | < 0.01 | 157 | 07 Nov 2014 |
| Seed | n/a | n/a | 633 µg/seed  (-) | 03 Jun 2014 | BBCH 00 | Whole Plant | < 0.01 | 57 | 30 Jul 2014 |
| BBCH 00 | Whole Plant | < 0.01 | 72 | 14 Aug 2014 |
| BBCH 00 | Cobs | < 0.01 | 105 | 16 Sep 2014 |
| BBCH 00 | Kernels | < 0.01 | 105 | 16 Sep 2014 |
| BBCH 00 | Whole cobs | < 0.01 | 105 | 16 Sep 2014 |
| BBCH 00 | Remaining plants | < 0.01 | 105 | 16 Sep 2014 |
| BBCH 00 | Whole Plant | < 0.01 | 132 | 13 Oct 2014 |
| BBCH 00 | Cobs | < 0.01 | 157 | 07 Nov 2014 |
| BBCH 00 | Kernels | < 0.01 | 157 | 07 Nov 2014 |
| BBCH 00 | Whole cobs | < 0.01 | 157 | 07 Nov 2014 |
| BBCH 00 | Remaining plants | < 0.01 | 157 | 07 Nov 2014 |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP = storage period

NR = not recorded

n/a = not applicable

* + 1. Magnitude of residues in livestock

No new data are submitted.

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data are submitted.

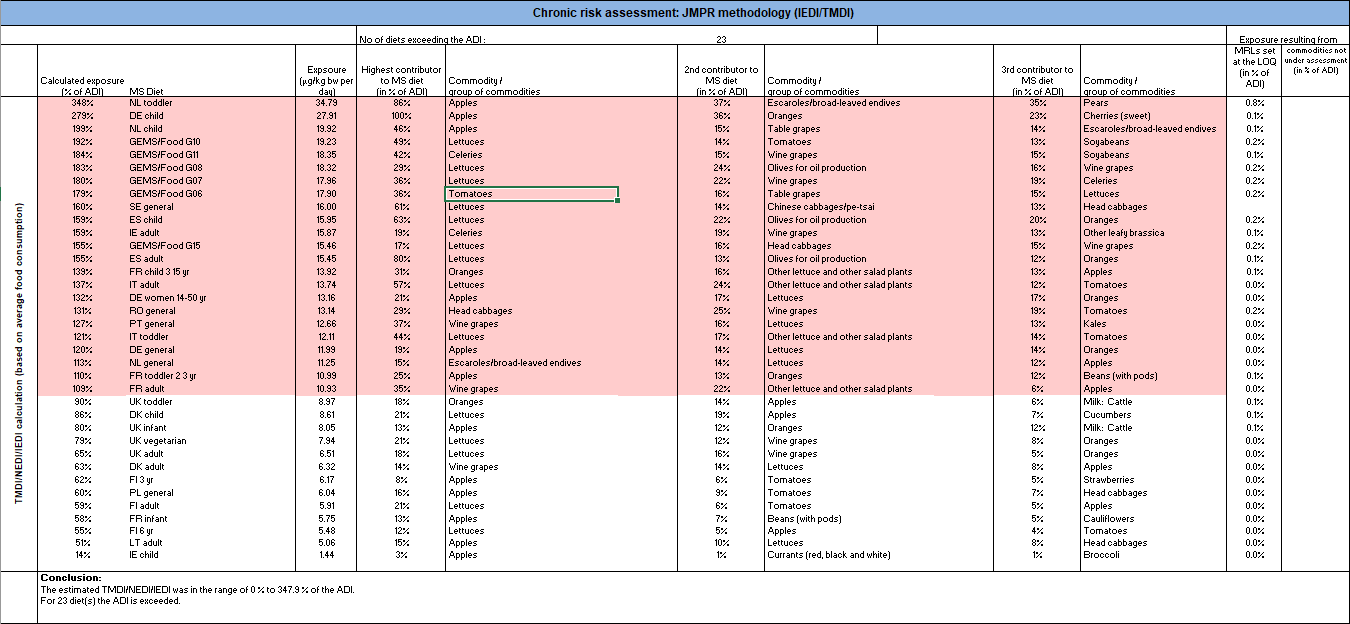
* + 1. Magnitude of residues in representative succeeding crops

No new data are submitted.

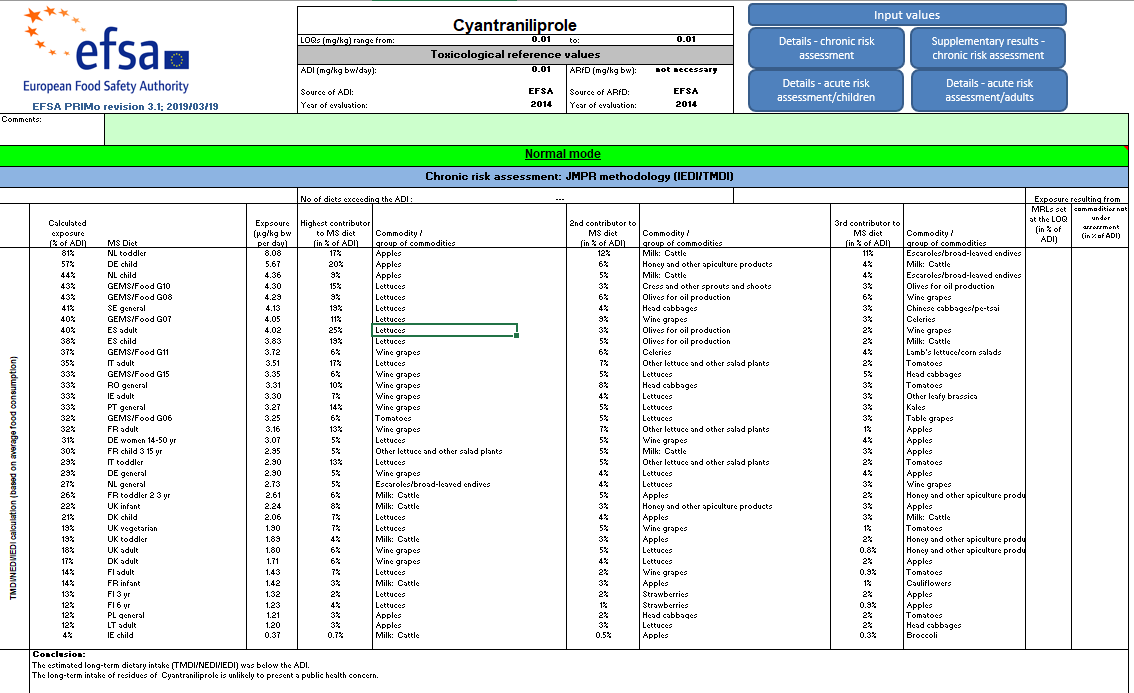
* + 1. Other/Special Studies

No new data are submitted.

1. Pesticide Residue Intake Model (PRIMo)
   1. TMDI calculations



* 1. IEDI calculations



* 1. IESTI calculations - Raw commodities

Because no ARfD was deemed necessary, acute risk assessment is not required.

* 1. IESTI calculations - Processed commodities

As quantifiable residues of cyantraniliprole are not expected in the treated crop, and the contribution of maize to the TMDI is <10% (see also 7.2.8), there is no need to investigate the effect of industrial and/or household processing.