

REASONED OPINION

Reasoned opinion on the modification of the existing MRL for cyprodinil in celery¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from Syngenta France SAS to modify the existing maximum residue level (MRL) for the active substance cyprodinil in celery. In order to accommodate for the intended uses of cyprodinil, France proposed to raise the existing MRL from the value of 5 mg/kg to 7 mg/kg. France drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the submitted data support a MRL proposal of 5 mg/kg for the proposed outdoor uses on celery and therefore, that there is no need to change the current MRL value of 5 mg/kg set under Regulation (EC) No 396/2005. The intended indoor use on celery was not adequately supported by residue data and therefore no MRL proposal could be made to accommodate the intended indoor use. Adequate analytical enforcement methods are available to control the residues of cyprodinil in celery. Based on the risk assessment results, EFSA concludes that the proposed use of cyprodinil on celery will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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KEY WORDS

cyprodinil, celery, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, anilinopyrimidine, fungicide

¹ On request from the European Commission, Question No EFSA-Q-2014-00936, approved on 10 March 2015.

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Suggested citation: EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing MRL for cyprodinil in celery. EFSA Journal 2015;13(3):4046, 23 pp. doi:10.2903/j.efsa.2015.4046

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, France, hereafter referred to as the evaluating Member State (EMS), received an application from Syngenta France SAS to modify the existing maximum residue level (MRL) for the active substance cyprodinil in celery. In order to accommodate for the intended uses of cyprodinil, France proposed to raise the existing MRL from the value of 5 mg/kg to 7 mg/kg. France drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 19 December 2014.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) (and its addenda) prepared under Council Directive 91/414/EEC, the Commission Review Report, the conclusion on the peer review of the pesticide risk assessment of the active substance cyprodinil, the JMPR Evaluation reports as well as the conclusions from the previous EFSA opinion under article 12 of Regulation (EC) No 396/2005.

The toxicological profile of cyprodinil was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg bw per day. It was deemed unnecessary to set an acute reference dose (ARfD).

The metabolism of cyprodinil in primary crops was investigated in three different crop groups. From these studies the peer review concluded to establish the residue definition for enforcement and for risk assessment on crops in the leafy metabolism group (to which celery belongs) as cyprodinyl.

EFSA concludes that the submitted supervised residue trials support a MRL proposal of 5 mg/kg for the proposed outdoor uses on celery and therefore, that there is no need to change the current MRL value of 5 mg/kg set under Regulation (EC) No 396/2005. The intended indoor use on celery was not adequately supported by residue data and therefore no MRL proposal could be made to accommodate the intended indoor use. Adequate analytical enforcement methods are available to control the residues of cyprodinil in celery at the validated LOQ of 0.02 mg/kg.

Studies investigating the nature of cyprodinil residues in processed commodities were assessed in the peer review and showed that the compound is hydrolytically stable under standard hydrolysis conditions. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

The occurrence of cyprodinil residues in rotational crops was investigated in the framework of the peer review and the previous EFSA opinion on cyprodinil under article 12 of Regulation (EC) No 396/2005. Based on the available information, it was concluded that following the intended use on celery, significant residue levels of metabolites CGA 321915 and NOA 422054 are likely to occur. As recommended in its previous EFSA opinion on the Article 12 MRL review, although CGA 321915 and NOA 422054 were not considered to be of any particular toxicological concern compared to the parent compound, because the toxicological data available are limited, EFSA concludes that Member States granting authorisations for cyprodinil on celery should consider the need to take appropriate risk mitigation measures (e.g. definition of a pre-plant interval of at least 120d) in order to avoid residues of cyprodinil metabolites CGA 321915 and NOA 422054, being present in rotational crops.

Residues of cyprodinil in commodities of animal origin were not assessed in the framework of this application, since celery is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). No long-term consumer intake concerns were identified for any of the European diets assessed. The total calculated intake accounted for up to 39 % of the ADI (German child). The contribution of residues in celery to the total consumer exposure accounted for a maximum of 0.3 % of the ADI (Irish adult). An acute consumer exposure assessment was not performed, due to the low acute toxicity of the active substance.

EFSA concluded that the proposed use of cyprodinil on celery will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

Thus EFSA proposes there is no need to amend the existing MRL as indicated in the summary table.

SUMMARY TABLE

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: cyprodinil				
270030	Celery	5	5	The submitted NEU and SEU outdoor trials do not support the change of the MRL value of 5 mg/kg currently set under Reg. (EC) No 396/2005. An insufficient number of trials were provided to support the use of cyprodinil under indoor conditions.

(a): According to Annex I of Regulation (EC) No 396/2005.

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BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company Syngenta France SAS⁶ to modify the existing MRL for the active substance cyprodinil in celery. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 19 December 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00936 and the following subject:

Cyprodinil – Application to set new MRLs in celery

France proposed to raise the existing MRL of cyprodinil in celery from the value of 5 mg/kg to 7 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the deadline for providing the reasoned opinion was 19 March 2015.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

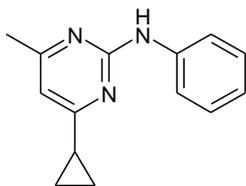
Cyprodinil is the ISO common name for 4-cyclopropyl-6-methyl-*N*-phenylpyrimidin-2-amine (IUPAC). The chemical structure of the compound is reported below.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

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Molecular weight: 225.3 g/mol

Cyprodinil is a fungicide belonging to the pyrimidine class. It is taken up via leaves and inhibits both the penetration and mycelial growth of *Ascomycetes*, *Basidiomycetes* and *Deuteromycetes*.

Cyprodinil was evaluated in the framework of Council Directive 91/414/EEC with France designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2006/64/EC⁷ which entered into force on 01 May 2007 for use only as a fungicide. In accordance with Commission Implementing Regulation (EU) No 540/2011⁸ cyprodinil is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. The representative uses evaluated in the peer review were foliar applications on winter wheat and apples. The Draft Assessment Report (DAR) of cyprodinil has been peer reviewed by EFSA (EFSA, 2005).

The EU MRLs for cyprodinil are established in Annex II of Regulation (EC) No 396/2005. The existing MRLs were reviewed by EFSA (EFSA, 2013b) and voted by the Standing Committee on Plants, Animals, Food and Feed (PAFF) – Pesticides residues, though the MRLs are not yet published in the Official Journal. The existing EU MRL for cyprodinil on celery is set at 5 mg/kg. Codex Alimentarius has established CXLs for a range of commodities, but a CXL has not been set for celery.

The details of the intended GAPs for cyprodinil are given in Appendix A.

⁷ Council Directive 2006/64/EC of 18 July 2006, amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, p. 107-111.

⁸ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (France, 2014), the Draft Assessment Report (DAR) (and its addenda) prepared under Council Directive 91/414/EEC (France, 2003, 2009), the Commission Review Report on cyprodinil (EC, 2010c), the conclusion on the peer review of the pesticide risk assessment of the active substance cyprodinil (EFSA, 2005), the JMPR Evaluation reports (FAO, 2003, 2009) as well as the conclusions from the previous EFSA opinion on cyprodinil under article 12 of Regulation (EC) No 396/2005 (EFSA, 2013b). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; FAO, 2009, OECD, 2011).

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of cyprodinil residues in plant commodities were assessed in the DAR and during the peer review under Directive 91/414/EEC (France, 2003, 2009; EFSA, 2005) and the previous EFSA opinion on cyprodinil under article 12 of Regulation (EC) No 396/2005 (EFSA, 2013b).

An analytical method using HPLC-UV was evaluated and validated for the determination of cyprodinil in plant matrices with an LOQ of 0.01 mg/kg in high water content (apple) and acidic commodities (grapes), and with an LOQ of 0.02 mg/kg in dry/starch commodities (wheat grain). Some limited ILV data for this method with UV detection were available for various high water content crops and wheat with an LOQ of 0.02 mg/kg. Confirmation and ILV for cyprodinil has been achieved by developing this method by changing from UV to MS/MS detection resulting in an HPLC-MS/MS method. This was acceptably validated with an LOQ of 0.01 mg/kg in high water content (lettuce and radish roots), acidic (grape), and dry (wheat grain and straw) commodities (France, 2003). The HPLC-MS/MS approach also included validation for commodities of high oil content (rape seed) although the recoveries were low (53 % to 79 %, average 70 %) at the higher fortification level. This method is fully acceptable to support all the authorised uses except high oil content commodities (almonds).

Additionally, the multi-residue DFG S19 method using GC-MS was demonstrated to be suitable for the determination of cyprodinil and was validated in high water content (tomatoes), high acid content (oranges), high oil content (rape seed) and dry/starch commodities (wheat grain) with an LOQ of 0.02 mg/kg (France, 2003). The ILV for this method was not accepted by the peer review because both validations were performed in the same laboratory.

In the framework of a previous MRL application, the above validation data were considered sufficient to address enforcement of residues in herbal infusions and spices of roots (EFSA, 2009); mainly on the basis of the DFG S19 method being validated in the four main crop groups at the same LOQ. EFSA is now aware that the multi residue method (DFG S19) did not have an acceptable ILV and therefore should not have considered the method adequate for the enforcement of the proposed MRLs. A validated analytical method for enforcement of cyprodinil in herbal infusions and spices is therefore still required.

The multi-residue QuEChERS method in combination with HPLC-MS/MS and GC/MS, as described by CEN (CEN, 2008), is also reported for analysis of cyprodinil only with an LOQ of 0.01 mg/kg in high water content, acidic and dry commodities (EURL, 2013). Detailed validation data were not

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

reported as they did not impact on the outcome of the assessment and validation data for high oil content commodities or spices were not available.

Consequently, also considering that a large number of the available residues trials were generated using an LOQ of 0.02 mg/kg, it is concluded that cyprodinil can be enforced in food of plant origin with an LOQ of 0.02 mg/kg in high water content, acidic and dry/starch commodities. Cyprodinil has also been analysed for successfully in rape seed however ILV data are not currently available for this high oil content commodity group and this is therefore required.

Since the commodity under consideration belongs to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for cyprodinil in celery are available.

1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin were not assessed in the current application, since celery is normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance cyprodinil was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2005). The data were sufficient to derive toxicological reference values for cyprodinil which are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
cyprodinil					
ADI	EFSA	2005	0.03 mg/kg bw per day	Rat, two year	100
ARfD	EFSA	2005	Not necessary		

Furthermore, metabolites CGA 321915 and NOA 422054 found in rotational crop were also tested. They were both of low acute toxicity ($LD_{50} >2000$ mg/kg bw) and no mutagenic potential was detected in an Ames test (EFSA, 2005).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of cyprodinil in primary crops was evaluated by France (France, 2003, 2009) and reviewed by EFSA (EFSA, 2005) in the framework of the peer review under Directive 91/414/EEC and the previous EFSA opinion on cyprodinil under article 12 of Regulation (EC) No 396/2005 (EFSA, 2013b). The metabolism of cyprodinil was investigated in three crop groups; in fruit crops (apple, peach and tomato), root crops (potato) and cereals (wheat), following foliar applications. The overview of the metabolism study designs is presented in Table 3-1.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Application and sampling details			
		Method	Rate (g/ha)	Sampling (DALA) ^(a)	Remarks
Fruit crops	apple	Foliar	3x 50 g/hl	61 (fruits, foliage)	-
	peach	Foliar	4x 27 4x 2700	1 (fruits, foliage)	-
	tomato	Foliar	2x 750	14 (fruits, harvest)	-
Root crops	potato	Foliar	3x 560	14 (tubers, foliage)	-
Cereals	wheat	Foliar	1x 750	plant autoradiography 0-35 days	-
	wheat	Foliar	750 + 500	41 (straw, husk, grain) ¹	-

(a): DALA: Days after last application

Based on these studies, the residue for enforcement and risk assessment in all plant commodities (including leafy crops which, is the crop group relevant for celery) was defined as cyprodinil only. Though EFSA (2013b) identified that the residue definition might require further consideration for root and tuber vegetables, including any uses on potatoes, if higher rates of use would be requested in the future, this is not pertinent to this intended use on celery. The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review and the article 12 review.

3.1.1.2. Magnitude of residues

In support of the MRL application, 4 northern and 4 southern European outdoor trials and 2 indoor trials on celery, were submitted. Based on the SEU outdoor trials, the EMS proposed to derive a MRL value of 7 mg/kg on celery. However, since the residue levels observed in northern and southern outdoor trials are not significantly different (FAO (2009), U-Test, 5%), EFSA proposes to merge the NEU and SEU dataset in order to derive an MRL of 5 mg/kg for celery.

Only two trials conducted under indoor conditions were submitted, therefore EFSA concludes that insufficient data are available to propose an MRL and to support the indoor use of cyprodinil on celery.

The results of the residue trials evaluated as being representative of the GAP, the related risk assessment input values (highest residue, median residue) and the MRL proposals, (all of which are for the same residue definition of cyprodinil), are summarised in Table 3-2.

The storage stability of cyprodinil was concluded upon in the EFSA conclusion (EFSA, 2005) and the previous EFSA opinion (EFSA, 2013b). Residues of cyprodinil were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 26 months in high water content commodities (peach, apple) and 24 months in high acid content commodities (grape, strawberries) and in dry/starch commodities (wheat). As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the supervised residue trial samples has been sufficiently validated and was proven to be fit for the purpose (France, 2014).

EFSA concludes that there is no need to change the MRL value of 5 mg/kg currently set on celery under Regulation (EC) No 396/2005, since the submitted datasets result in a MRL proposal of 5 mg/kg for the intended field use on celery in SEU and NEU. The data base of two results from glasshouse trials at two sites is insufficient to propose MRLs for the indoor use on celery.

Table 3-2: Overview of the available residues trials data

Crop (Trial GAPs)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (c)	MRL proposals (mg/kg)	HR (mg/kg) (d)	STMR (mg/kg) (e)
Celery (2x 375 g/ha, PHI 14 d)	NEU	0.17; 0.75; 0.79; 1.71	Northern and Southern datasets not significantly different (U-Test, 5%), MRL, STMR and HR derived from the merged data. MRL _{OECD} : 4.9/5.0	5.0	3.12	0.75
	SEU	0.24; 0.37; 0.74; 3.12				
Celery (2x 375 g/ha, PHI 14 d)	Indoor	1.0; 2.01	Data base insufficient to propose an MRL and to support the indoor use of cyprodinil on celery.	-	-	-

(a): **NEU**: Outdoor trials conducted in northern Europe, **SEU**: Outdoor trials conducted in southern Europe, **Indoor**: indoor EU trials or **Country code**: if non-EU trials (EC, 2011).

(b): Individual residue levels considered for MRL calculation are reported in ascending order determined as cyprodinil

(c): Any information/comment supporting the decision and OECD MRL calculation (e.g. MRL_{OECD}: 0.82/0.9; unrounded/rounded values)

(d) **STMR**: Median value of the individual trial results according to residue definition for risk assessment.

(e) **HR**: Highest value of the individual trial results according to the residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of cyprodinil residues was investigated under standard hydrolysis conditions. The studies were reported in the DAR and in the conclusion on the peer review (France, 2003, 2009; EFSA, 2005) and the previous EFSA opinion on cyprodinil under article 12 of Regulation (EC) No 396/2005 (EFSA, 2013b). The conclusion of these assessments was that cyprodinil is hydrolytically stable under the representative processing conditions of pasteurisation, baking/brewing/boiling and sterilisation, so these processes are not expected to have a significant impact on the composition of residues in matrices of plant origin. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be cyprodinil.

Specific studies to assess the magnitude of cyprodinil residues during the processing of celery are not necessary as the crop is mostly eaten raw.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Celery can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. According to the soil degradation studies evaluated in the framework of the peer review, the highest DT₉₀ value of cyprodinil based on the field study results was up to 814 days in acidic soils, which is higher than the trigger value of 100 days (EFSA, 2005, 2013b). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of cyprodinil in rotational crops was evaluated by France (France, 2003, 2009) and reviewed by EFSA (EFSA, 2005) in the framework of the peer review under Directive 91/414/EEC and the previous EFSA opinion (EFSA, 2013b). The data on metabolism and distribution of cyprodinil in succeeding crops confirmed the presence of the plant metabolites NOA 422054 and CGA 321915 which were found at measurable levels at the earliest plant back interval (PBI) of 30 days, whilst parent cyprodinil occurred rarely. However, as none of these metabolites were found to be of toxicological concern, it was concluded in the peer review not to include these metabolites in the residue definition for plants assuming that short plant-back intervals were not expected to occur in practice for the crops supported in the framework of the peer review (EFSA, 2005). However with a PHI of 14 days a plant back interval of 30 days represents what might happen when a crop is planted following celery cultivation.

3.1.2.3. Magnitude of residues

In addition to the confined rotational crop studies, five rotational field trials performed at application rates ranging from 750 g/ha to 2240 g/ha (from N to 3N of the intended annual dose on celery) were evaluated in the framework of the peer review (France, 2003, 2009, EFSA, 2005) and in the previous EFSA opinion (EFSA, 2013b).

In the first field study performed in California (USA) cyprodinil was applied to bare soil at 4x 560 g/ha (a total of 2240 g/ha) and lettuce, turnips and wheat were sown or planted as succeeding crops 30, 90, 150 and 210 DAT. Samples were analysed for cyprodinil parent only. No cyprodinil residues were found above the LOQ in any of the samples 30 DAT, and the samples for the longer plant back intervals were therefore not analysed.

In the other four studies, performed in Northern Europe, cyprodinil was applied once to wheat at 750 g/ha. Wheat, lettuce and radishes were planted as succeeding crops 28-30 or 35-37 DAT. Lettuce and radishes were also planted 112-114 or 120 DAT while wheat was additionally planted 314-315 or 331-370 DAT. Crop samples were analysed for parent cyprodinil and for metabolites CGA 321915 and NOA 422054. Both metabolites were encountered in measurable levels in the succeeding crops for

the short plant back intervals (30 DAT). Cyprodinil itself occurred very rarely and only at the earliest replanting interval at 0.01 mg/kg. Residues of NOA 422054 were up to 0.14 mg/kg in radish tops, 0.04 mg/kg in lettuces and 0.07 mg/kg in wheat forage from 30 DAT and with the total application rate of 750 g/ha. The corresponding maximum residue of CGA 321915 was 0.03 mg/kg in radish leaves. These metabolites were rarely found at the later replanting timings, and at lower levels when found (up to 0.02 mg/kg).

Based on these studies it is concluded that significant residues levels of cyprodinil are not expected to be present in rotational crops. In contrast, and for short plant back intervals (*ca.* 30 days) measurable levels of metabolites CGA 321915 and NOA 422054 would be expected in rotational crops, following the use of cyprodinil on celery according to the proposed GAPs.

As recommended in its previous EFSA opinion on the Article 12 MRL review (EFSA, 2013b), although CGA 321915 and NOA 422054 were not considered to be of any particular toxicological concern compared to the parent compound, because the toxicological data available are limited, EFSA concludes that Member States granting authorisations for cyprodinil on celery should consider the need to take appropriate risk mitigation measures (e.g. definition of a pre-plant interval of at least 120d) in order to avoid residues of cyprodinil metabolites CGA 321915 and NOA 422054, being present in rotational crops.

3.2. Nature and magnitude of residues in livestock

Since celery is not normally fed to livestock, the nature and magnitude of cyprodinil residues in livestock is not assessed in the framework of this application (EC, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁰ (EFSA, 2007).

For the calculation of the chronic exposure, EFSA used STMR values as derived from the residue trials on celery (see Table 3-2), and the median residue values for commodities covered by previously issued EFSA reasoned opinions (EFSA, 2013a or b). The residue definition used for the risk assessment in plant commodities was cyprodinil. The risk assessment residue definition for the animal commodities assessed, was sum of cyprodinil and CGA 304075 expressed as cyprodinil (see EFSA, 2013b),

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

An acute consumer exposure assessment was not performed, due to the low acute toxicity of the active substance.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

¹⁰ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: {RA RD}				
Cucurbits inedible peel	0.02	STMR (EFSA, 2013a)	An acute risk assessment was not performed as the setting of and ARfD was deemed unnecessary for cyprodinil	
Celery	0.75	STMR (current evaluation)		
Other plant and animal commodities	STMR and MRLs as set out in table 4.2 in EFSA (2013b)			

The estimated exposure was then compared with the toxicological reference value derived for cyprodinil (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for up to 39 % of the ADI (German child diet). The contribution of residues in celery to the total consumer exposure accounted for a maximum of 0.3 % of the ADI (Irish adult diet).

EFSA concludes that the intended use of cyprodinil on celery will not result in a consumer exposure exceeding the toxicological reference value from the consumption of treated celery and therefore is unlikely to pose a public health concern.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) (and its addenda) prepared under Council Directive 91/414/EEC, the Commission Review Report, the conclusion on the peer review of the pesticide risk assessment of the active substance cyprodinil, the JMPR Evaluation reports as well as the conclusions from the previous EFSA opinion under article 12 of Regulation (EC) No 396/2005.

The toxicological profile of cyprodinil was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg bw per day. It was deemed unnecessary to set an acute reference dose (ARfD).

The metabolism of cyprodinil in primary crops was investigated in three different crop groups. From these studies the peer review concluded to establish the residue definition for enforcement and for risk assessment on crops in the leafy metabolism group (to which celery belongs) as cyprodinyl.

EFSA concludes that the submitted supervised residue trials support a MRL proposal of 5 mg/kg for the proposed outdoor uses on celery and therefore, that there is no need to change the current MRL value of 5 mg/kg set under Regulation (EC) No 396/2005. The intended indoor use on celery was not adequately supported by residue data and therefore no MRL proposal could be made to accommodate the intended indoor use. Adequate analytical enforcement methods are available to control the residues of cyprodinil in celery at the validated LOQ of 0.02 mg/kg.

Studies investigating the nature of cyprodinil residues in processed commodities were assessed in the peer review and showed that the compound is hydrolytically stable under standard hydrolysis conditions. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable.

The occurrence of cyprodinil residues in rotational crops was investigated in the framework of the peer review and the previous EFSA opinion on cyprodinil under article 12 of Regulation (EC) No 396/2005. Based on the available information, it was concluded that following the intended use on celery, significant residue levels of metabolites CGA 321915 and NOA 422054 are likely to occur. As recommended in its previous EFSA opinion on the Article 12 MRL review, although CGA 321915 and NOA 422054 were not considered to be of any particular toxicological concern compared to the parent compound, because the toxicological data available are limited, EFSA concludes that Member States granting authorisations for cyprodinil on celery should consider the need to take appropriate risk mitigation measures (e.g. definition of a pre-plant interval of at least 120d) in order to avoid residues of cyprodinil metabolites CGA 321915 and NOA 422054, being present in rotational crops.

Residues of cyprodinil in commodities of animal origin were not assessed in the framework of this application, since celery is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). No long-term consumer intake concerns were identified for any of the European diets assessed. The total calculated intake accounted for up to 39 % of the ADI (German child). The contribution of residues in celery to the total consumer exposure accounted for a maximum of 0.3 % of the ADI (Irish adult). An acute consumer exposure assessment was not performed, due to the low acute toxicity of the active substance.

EFSA concluded that the proposed use of cyprodinil on celery will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: cyprodinil				
270030	Celery	5	5	The submitted NEU and SEU outdoor trials do not support the change of the MRL value of 5 mg/kg currently set under Reg. (EC) No 396/2005. An insufficient number of trials were provided to support the use of cyprodinil under indoor conditions.

(a): According to Annex I of Regulation (EC) No 396/2005.

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APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d-f)	conc. a.s. (i)	Method kind (f-h)	Growth stage & season (j)	number min-max (k)	interval min-max	g as/hL min-max	Water L/ha min-max	g a.s./ha min-max		
Celery	N & S E.U.	F	Fungal diseases	WG	375 g/kg	Foliar spray	BBCH 14-49	2	10		300-600	375	14	
Celery	N & S E.U.	G	Fungal diseases	WG	375 g/kg	Foliar spray	BBCH 14-49	2	10		300-600	375	14	

Remarks:

- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

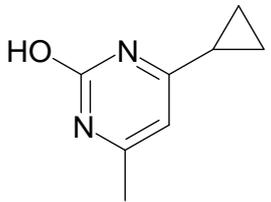
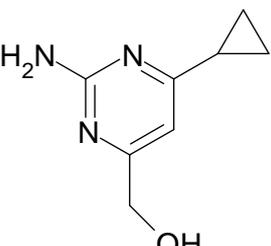
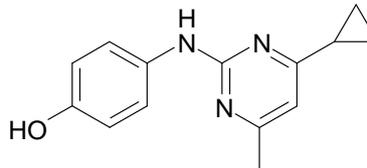
Appendix B. Pesticide Residue Intake Model (PRIMO)

Cyprodinil									
Status of the active substance:		Included		Code no.		Prepare workbook for refined calculations			
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.03		ARfD (mg/kg bw):		n.n.			
Source of ADI:		EFSA		Source of ARfD:		EFSA			
Year of evaluation:		2005		Year of evaluation:		2005			
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				5 39					
				No of diets exceeding ADI:					

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRs at LOQ (in % of ADI)	
38.6	DE child	19.7	Apples	2.9	Table grapes	2.1	Spinach		
30.0	NL child	10.3	Apples	3.8	Spinach	2.1	Scarole (broad-leaf endive)		
25.5	WHO Cluster diet B	4.0	Wine grapes	3.7	Lettuce	3.7	Wheat		
23.4	FR toddler	7.3	Spinach	4.3	Apples	3.6	Carrots		
20.3	IE adult	3.1	Barley	2.8	Wine grapes	1.3	Apples		
19.4	FR infant	4.6	Spinach	4.1	Apples	3.9	Carrots		
16.4	WHO cluster diet E	3.6	Wine grapes	2.0	Barley	1.7	Wheat		
16.3	DK child	3.8	Apples	2.4	Wheat	2.0	Carrots		
15.6	FR all population	8.9	Wine grapes	1.4	Wheat	0.9	Lettuce		
15.1	ES adult	5.5	Lettuce	1.3	Apples	1.2	Barley		
14.4	ES child	4.3	Lettuce	1.9	Wheat	1.9	Apples		
13.9	WHO regional European diet	3.9	Lettuce	1.3	Wheat	1.1	Apples		
13.4	PT General population	5.6	Wine grapes	1.7	Apples	1.7	Wheat		
13.0	IT kids/toddler	3.0	Lettuce	2.9	Wheat	1.4	Apples		
12.9	NL general	1.9	Apples	1.5	Spinach	1.4	Wine grapes		
12.8	IT adult	3.9	Lettuce	1.8	Wheat	1.3	Apples		
12.4	WHO Cluster diet F	3.1	Lettuce	1.6	Wheat	1.5	Barley		
10.6	WHO cluster diet D	2.8	Wheat	1.1	Apples	0.8	Wine grapes		
9.8	SE general population 90th percentile	1.7	Apples	1.4	Wheat	1.3	Carrots		
9.3	UK Toddler	2.8	Apples	1.7	Wheat	0.8	Carrots		
9.1	UK Infant	2.6	Apples	2.0	Carrots	1.1	Wheat		
8.1	DK adult	3.1	Wine grapes	1.3	Apples	0.9	Wheat		
7.8	UK vegetarian	1.8	Wine grapes	1.5	Lettuce	1.0	Apples		
7.4	PL general population	3.3	Apples	0.7	Table grapes	0.5	Tomatoes		
7.0	LT adult	3.0	Apples	0.7	Lettuce	0.5	Rye		
6.8	UK Adult	2.4	Wine grapes	1.2	Lettuce	0.7	Wheat		
4.8	FI adult	0.8	Lettuce	0.7	Wine grapes	0.7	Apples		
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.									
A long-term intake of residues of Cyprodinil is unlikely to present a public health concern.									

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
Acute risk assessment is not necessary.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1		*)	**)	IESTI 2		*)	**)	IESTI 1		*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	IESTI 1		*)	**)	IESTI 2		*)	**)	IESTI 1		*)	**)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
As no ARfD was considered necessary, it is concluded that the short-term intake of Cyprodinil residues is unlikely to present a public health concern.												

Appendix C. List of metabolites and related structural formula

Code/Trivial name	IUPAC name	Structural formula
CGA 321915	4-cyclopropyl-6-methyl-pyrimidin-2-ol	 <p>The structure shows a pyrimidine ring with a methyl group at position 6, a cyclopropyl group at position 4, and a hydroxyl group at position 2.</p>
NOA 422054	(2-amino-6-cyclopropyl-pyrimidin-4-yl) methanol	 <p>The structure shows a pyrimidine ring with an amino group at position 2, a cyclopropyl group at position 6, and a hydroxymethyl group at position 4.</p>
CGA 304075	4-[(4-cyclopropyl-6-methyl-pyrimidin-2-yl) amino] phenol	 <p>The structure shows a phenol ring with a hydroxyl group at position 4 and an amino group at position 1. The amino group is attached to a pyrimidine ring that has a methyl group at position 6 and a cyclopropyl group at position 4.</p>

ABBREVIATIONS

ADI	acceptable daily intake
AIR	Annex I Renewal
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CIRCA	(EU) Communication & Information Resource Centre Administrator
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
GS	growth stage
ha	hectare

hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
mo	month
MRL	maximum residue level
MS	Member States
-MS	mass spectrometry detector
MS/MS	tandem mass spectrometry
MW	molecular weight
NEU	northern European Union
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
Pow	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R _{ber}	statistical calculation of the MRL by using a non-parametric method
R _{max}	statistical calculation of the MRL by using a parametric method
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RPF	relative potency factor
SANCO	Directorate-General for Health and Consumers
SCPAFF	Standing Committee on Plants, Animals, Food and Feed, (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)

SEU	southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet (detector)
WHO	World Health Organization
WG	water dispersible granule
wk	week
YF	yield factor
yr	year