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Modification of the existing maximum residue levels for pyrimethanil in table grapes, garlic and honey

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Ascenza Agro S.A. submitted a request to the competent national authority in Greece to modify the existing maximum residue levels (MRL) for the active substance pyrimethanil in table grapes, garlic and honey. The data submitted in support of the request were found to be sufficient to derive MRL proposals for table grapes, garlic and honey. Adequate analytical methods for enforcement are available to control the residues of pyrimethanil in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of pyrimethanil according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: pyrimethanil, table grapes, garlic, honey, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Ascenza Agro S.A. submitted an application to the competent national authority in Greece (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance pyrimethanil in table grapes, garlic and honey.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 7 June 2021. The appointed EMS Greece assessed the dossier and declared its admissibility on 8 December 2021. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 25 August 2022 to 15 September 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the 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 3 November 2022. To accommodate for the intended uses of pyrimethanil, the EMS proposed to raise the existing MRL for table grapes from 5 mg/kg to 6 mg/kg and to raise the existing MRLs for garlic and honey from the limit of quantification (LOQ) to 0.04 and 0.3 mg/kg respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified a data gap, which was requested from the EMS. On 30 March 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 8 June 2023, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of pyrimethanil in primary crops following foliar application was investigated in crops belonging to the groups of fruit crops, root crops and leafy crops. The metabolic pathway was considered qualitatively similar throughout all crop groups and treatments with parent pyrimethanil being the main residue.

In rotational crops, metabolites were identified at levels equivalent or higher than the parent compound.

Studies investigating the effect of processing on the nature of pyrimethanil (hydrolysis studies) demonstrated that the active substance is stable.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological relevance of metabolites, the residue definitions for plant products were proposed as 'pyrimethanil' for enforcement and risk assessment. These residue definitions are applicable to primary crops and processed products. EFSA concluded that for the crops assessed in this application, metabolism of pyrimethanil in primary and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical enforcement methods are available to quantify residues in honey and in the commodities assessed in this application according to the enforcement residue definition. The methods enable the quantification of residues at 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals of 6 mg/kg for table grapes and 0.03 mg/kg for garlic.

The occurrence of pyrimethanil residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review. Submitted rotational crop field studies indicate that no residues of pyrimethanil or metabolite C 621 312 were detected in rotational crops above the LOQ of 0.05 mg/kg. The MRL review concluded that the possible presence of residual compounds resulting from the use of pyrimethanil in rotational crops is limited to low amounts and that the resulting toxicological burden can be considered minor. The field rotational study was affected by a number of deficiencies related to the design of the study and its compliance with the current guidance documents. Pending the outcome of the renewal of the approval of pyrimethanil and in line with the previous assessments, EFSA concludes that the intended use on garlic would not result in significant residues in rotational crops.

Specific studies investigating the magnitude of pyrimethanil residues in processed commodities are not required, as the individual contribution of residues in the commodities under consideration to the total theoretical maximum daily intake (TMDI) is below 10% of the acceptable daily intake (ADI).

Residues of pyrimethanil in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

Studies investigating the magnitude of residues in honey were submitted in the current application. When pyrimethanil is used on melliferous crops at the intended or authorised application rates in Europe, residues in honey cannot be excluded. The available residue trials are sufficient to derive an MRL proposal of 0.3 mg/kg for honey.

The toxicological profile of pyrimethanil was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.17 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. EFSA notes that the toxicological assessment of pyrimethanil will be revised in the renewal of the approval process of pyrimethanil.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

The estimated long-term dietary intake accounted for a maximum of 26% of ADI (German child diet). The contribution of residues expected in table grapes, garlic and honey to the overall long-term exposure accounted individually for less than 1% of the ADI.

EFSA concluded that the proposed use of pyrimethanil on table grapes, garlic and residues in honey from the intended and authorised uses of pyrimethanil on melliferous crops will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 together with the assessment of confirmatory data following the review of the MRLs according to Article 12 of Regulation (EC) No 396/2005 is currently ongoing. The conclusions reported in this reasoned opinion may need to be reconsidered in light of the outcome of the peer review for renewal of the approval.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: pyrimethanil				
0151010	Table grapes	5	6	The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely.
0220010	Garlic	0.01*	0.03	The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers unlikely.
1040000	Honey and other apiculture products[(b)]	0.05*	0.3	The submitted data are sufficient to derive an MRL proposal for honey use. Risk for consumers unlikely.

MRL: maximum residue level; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for pyrimethanil in table grapes, garlic and honey. The detailed description of the intended uses of pyrimethanil in SEU on table grapes and garlic which are the basis for the current MRL application, is reported in Appendix A. The current MRL application on honey is not linked to one specific good agricultural practice (GAP) but is related to the existing uses in crops that might be attractive to bees and that are a potential source for residues of pyrimethanil in honey. The worst-case GAP was identified by the applicant.

Pyrimethanil is the ISO common name for *N*-(4,6-dimethylpyrimidine-2-yl)aniline (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Pyrimethanil was evaluated in the framework of Directive 91/414/EEC[1] with Austria designated as rapporteur Member State (RMS) for the representative uses as a foliar spray application on grapes, apples and protein peas. The draft assessment report (DAR) prepared by the RMS (Austria, 2004, 2005) has been peer reviewed by EFSA (EFSA, 2006). Pyrimethanil was approved[2] for the use as fungicide on 1 June 2007. The process of renewal of the first approval is currently ongoing.

The EU MRLs for pyrimethanil are established in Annex II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued two reasoned opinions on the modification of MRLs for pyrimethanil (EFSA, 2016a, 2018a). The proposals from these reasoned opinions have been considered in recent MRL regulations.[4] In addition, certain Codex MRLs have been taken over in the EU legislation in 2015 and 2017.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[5], the applicant Ascenza Agro S.A. submitted on 07 June 2021 an application to the competent national authority in Greece, alongside the dossier containing the supporting data using the IUCLID format.

The appointed evaluating Member State (EMS) Greece assessed the dossier and declared its admissibility on 8 December 2021. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 25 August 2022 to 15 September 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 3 November 2022. To accommodate for the intended uses of pyrimethanil, the EMS proposed to raise the existing MRL for table grapes from 5 mg/kg to 6 mg/kg and to raise the existing MRLs in garlic and honey from the limit of quantification (LOQ) to 0.04 mg/kg and 0.3 mg/kg respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified a data gap, which was requested from the EMS. On 30 March 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 8 June 2023 (Greece, 2022), which replaced the previously submitted evaluation report.

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, pp. 1–32.
[2] Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances. OJ L 235, 30.8.2006, pp. 17–22.
[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, 16.3.2005, pp. 1–16.
[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
[5] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, pp. 1–28.

EFSA based its assessment on the revised evaluation report submitted by the EMS (Greece, 2022), the DAR and its addendum (Austria, 2004, 2005) prepared under Council Directive 91/414/EEC, the Commission review report on pyrimethanil (European Commission, 2010b), the conclusions on the EU pesticides peer review, Article 10 EFSA reasoned opinions, the MRL review of the active substance pyrimethanil and JMPR assessments (EFSA, 2006, 2010, 2011, 2014, 2016a,b; FAO, 2007, 2013, 2015, 2018a).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a,b,c,d,e,f,g, 2010a, 2020, 2021; OECD, 2011). 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 546/2011[7].

As the EU pesticides peer review of the active substance in accordance with Regulation (EC) No 1107/2009 together with the assessment of confirmatory data following the review of the MRLs according to Article 12 of Regulation (EC) No 396/2005 is currently ongoing, the conclusions reported in this reasoned opinion may need to be reconsidered in light of the outcome of the peer review for renewal of the approval.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Greece, 2022) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[8]

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of pyrimethanil in primary crops has been investigated in the framework of the EU pesticides peer review following foliar as well as soil application on fruit crops (tomatoes, apples and grapes), root crops (carrots) and leafy crops (lettuce) (EFSA, 2006). It was concluded that the metabolic pathway of pyrimethanil is qualitatively similar throughout all crop groups and treatments with parent pyrimethanil being the main residue. For the intended uses, the metabolic behaviour of pyrimethanil in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Garlic can be grown in rotation with other crops and therefore the investigation of possible occurrence of residues of pyrimethanil and its metabolites in succeeding crops is required.

According to the soil degradation studies, the $DT_{90field}$ of 179 days was estimated for pyrimethanil in the framework of the peer review. In addition, the soil metabolite 2-amino-4,6-dimethylpyrimidine (AE F132593) was considered to be moderately to highly persistent with DT_{90lab} value of 49–331 days (EFSA, 2006). During the EU pesticides peer review, a confined rotational crop study was conducted on radish, lettuce and wheat following an application of 2,400 g a.s./ha ^{14}C-pyrimidyl labelled pyrimethanil to bare soil (EFSA, 2006). The crops were planted/sowed 30, 130 and 300 days after treatment.

In contrast to the metabolism in primary crops, several metabolites were identified at a level equivalent or higher than that of the parent compound. Identification of metabolites was mainly carried out in the samples from plots with crops planted 30 days after treatment. The metabolite generally present at highest levels was 2-anilino-4,6-dihydroxymethylpyrimidine (C 621 312).

[6] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, pp. 1–66.

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

[8] Background documents to this reasoned opinion are published on Open. EFSA and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2021-00745

Metabolite AE F132593 was found in all plant parts at PBI 30 days except tuber root. The amounts of pyrimethanil and its metabolites found in edible parts of plants sowed or planted 30 days after ageing period were such that quantifiable residue levels could be expected in case of early installation of rotational crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of pyrimethanil was investigated in the framework of the EU pesticides peer review (EFSA, 2006). These studies showed that pyrimethanil is stable under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods using gas chromatography with mass spectrometry (GC–MS) quantification for the determination of pyrimethanil residues were assessed during the EU pesticides peer review (EFSA, 2006). Methods were concluded valid to enforce pyrimethanil residues in high-water, high-acid, high-oil and dry/high-starch content commodities at the limit of quantification (LOQ) of 0.05 and 0.01 mg/kg. Under the Article 12 MRL review, a Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) was reported as being validated for the determination of pyrimethanil in high-water, high acid content and dry commodities at the LOQ of 0.01 mg/kg (EFSA, 2011). In addition, in the framework of the MRL application of pyrimethanil in leeks (EFSA, 2016a), validation data for a method using a liquid chromatography with tandem mass spectrometry (LC–MS/MS) was provided in high-water, high-acid, high-oil content and dry/high-protein commodities at the LOQ of 0.01 mg/kg. The methods are sufficiently validated for the determination of residues of pyrimethanil in the commodities under consideration.

EFSA notes that the extraction efficiency for the analytical methods applied for enforcement is not proven as indicated according to the requirements of the extraction efficiency Guidance (European Commission, 2023[9]) thus introducing additional uncertainty for the present assessment. To satisfy the current criteria of the guidance, further investigation on this matter would be required. EFSA would therefore recommend reconsidering the identified uncertainties in this section by the peer review for the renewal of approval of the active substance.

1.1.5. Storage stability of residues in plants

The storage stability of pyrimethanil in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and previous MRL applications (EFSA, 2006, 2016a). Residues of pyrimethanil were found to be stable in high-oil content commodities at $\leq -18°C$ for 24 months (EFSA, 2016a). In high-acid, high-water and high-protein content commodities, stability of residues was shown for at least 12 months at $\leq -18°C$ (EFSA, 2006).

It is concluded that in the plant commodities under consideration, which belong to high-acid and high-water content matrices, the freezer storage stability of pyrimethanil is addressed for 12 and 24 months, respectively.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed for primary crops and processed commodities (EFSA, 2006):

- residue definition for risk assessment: **pyrimethanil**
- residue definition for enforcement: **pyrimethanil**

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

[9] The previous revision 4 of SANTE/2017/10632, the technical guidance on extraction efficiency, was applicable at the date of submission of the IUCLID application (European Commission, 2022). Since then, further precisions on its applicability were addressed in the revised version 5. Since the revision 5 does not contain any new elements or obligations, EFSA took into consideration this newly released version directly.

For rotational crops, the residue definition shall be confirmed in the context of the current renewal of the approval of the active substance that is currently ongoing.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended SEU uses in table grapes and garlic, the applicant submitted residue trials performed on grapes, garlic and onion (Greece, 2022). The samples were analysed for the parent compound achieving an LOQ of 0.01 mg/kg. According to the EMS, the methods of analysis used to analyse the residue trial samples were sufficiently validated and were fit for purpose (Greece, 2022). All samples of these residue trials prior to analysis were stored under conditions for which the integrity of the samples has been demonstrated. The extraction efficiency of the methods applied for the residue trials was not proven according to the requirements of the extraction efficiency Guidance (European Commission, 2023), and remains an additional uncertainty.

Garlic

SEU, outdoor: 2 × 800 g pyrimethanil/ha, 10–12 day-interval between applications, BBCH from 10 to 49, preharvest interval (PHI): 14 days.

In support of the MRL application in garlic, the applicant submitted four residue trials performed on garlic and eight residue trials on onion. All the trials were GAP compliant and performed in different countries in southern Europe during the growing seasons of 2018 and 2019.

EMS and applicant proposed to derive an MRL from the combined data set of onions and garlic, nevertheless, EFSA is of the opinion that as garlic is a minor crop and four trials are sufficient to derive an MRL, the data sets of both crops should not be combined. An MRL of 0.03 mg/kg was derived using only the four garlic residue trials. This decision was in line with the as low as reasonably achievable (ALARA) principle, noting that the MRL derived from a combined dataset and proposed by the EMS and the applicant would be higher (0.04 mg/kg).

Table grapes

SEU, outdoor: 2 × 1000 g pyrimethanil/ha, 14 day-interval between applications, BBCH from 62 to 81, preharvest interval (PHI): 21 days.

In support of the MRL application in table grapes, the applicant submitted eight residue trials on grapevines. All the trials were GAP compliant and performed in different countries in southern Europe during the growing seasons of 2018 and 2019.

Among the trials, two (F/06/002/19 and F/06/004/19) were carried out at locations that were geographically close to each other, approximately 6 km apart and with close treatment dates (7 days). According to the EU guidance document on extrapolation, it is recommended that trial sites be at least 20 km apart to account for the variability in the production system unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc. (European Commission, 2020).

To establish the independence of these two trials, the applicant presented the following arguments:

- Different agronomical practices: In one trial, the leaves were removed before the second treatment to facilitate fruit development, while in the other trial, the foliage protected the bunches during both treatments. This difference in agronomical practice can affect the amount of pesticide that reaches the fruit, as foliage can intercept part of the sprayed product.
- Distinct soil types: The two locations featured different soil types, namely clayey soil and silt-loam soil. Clayey soil comprises very fine clay particles and has a high water-holding capacity, whereas silt-loam soil consists mainly of intermediate-sized particles and is fairly well drained.
- Varying rainfall: One of the trials experienced slightly higher rainfall compared to the other.
- Different grape varieties: Each trial employed a different grape variety, which exhibited morphological differences, including variations in bunch and fruit sizes, colour, shape and peel thickness.

After reviewing this justification, EFSA accepted this deviation and considered both trials as independent. The number of trials for table grapes was therefore considered sufficient to derive an MRL proposal of 6 mg/kg in support of the intended SEU use of pyrimethanil.

1.2.2. Magnitude of residues in rotational crops

A study conducted within the framework of the EU pesticide peer review (EFSA, 2006) investigated the potential transfer of pyrimethanil residues from primary crop treatments to crops grown in rotation. The study focused on lettuce as the target crop (2 × 0.8 kg a.s./ha; BBCH 16–19 and BBCH 43–47 with an interval of 10–11 days and a PHI of 14 days). After harvesting the main crops (lettuce), lettuce and brassica (cauliflower and curly kale) were planted 21–64 days after the last application and winter wheat was sown 18–21 days after the last application. The succeeding crops were sampled at harvest (lettuce: PHI = 70–119 days, brassica: 109–249 days and winter wheat (straw and grain): PHI = 321–330 days).

No residues of pyrimethanil or metabolite C 621 312 were detected above the LOQ (0.05 mg/kg). However, it should be noted that the study has some limitations it may not be fully representative of the proposed use on garlic. Firstly, lettuce has higher foliar interception compared to garlic (European Commission, 2014), potentially reducing the amount of pesticide that reaches the soil and becomes available for rotational crops. Also, the representative crops grown in rotation belong to the group's leafy vegetables and small grains and the crop group of root vegetables was not represented in the study. Furthermore, additional rotational intervals have not been investigated as the study only covers circumstances of crop failure or closely rotated crops. It is also worth mentioning that the study's LOQ was set at 0.05 mg/kg, while current analytical methods can enforce residues at a lower LOQ of 0.01 mg/kg.

In the framework of the MRL review (EFSA, 2011), it was concluded that the possible presence of residual compounds resulting from the use of pyrimethanil in rotational crops is limited to low amounts and that the resulting toxicological burden can be considered minor. Consequently, a plant-back restriction was not deemed necessary. Despite the deficiencies identified in the study, EFSA concludes it is unlikely that the intended use in garlic would result in significant residues in rotational crops. This is in line with previous EFSA opinions and the fact that garlic belongs to the minor crop category and is grown on a small scale. Nevertheless, EFSA recommends that the magnitude of pyrimethanil residues in rotational crops is further investigated in the framework of the renewal of the approval of pyrimethanil taking into account all the European uses of the substance. The renewal of the approval is currently ongoing.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of pyrimethanil residues in processed commodities were not provided for the commodities under assessment and were not considered necessary according to Regulation (EU) 544/2011 as the contribution of residues in the crops under consideration is individually below 1% of the ADI.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for table grapes and garlic (see Appendix B.1.2.1). In Section 4, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant, as the crops under assessment are not used for feed purposes.

3. Residues in honey

3.1. Nature of residues in honey

Honey is a product produced by bees from sugary secretions of plants (floral nectar mainly). In the absence of specific metabolism studies with honey bees, the metabolic profile in primary and rotational crops and the degradation of the active substance under standard hydrolysis conditions were taken into account. Based on the available information, it is considered likely that the nature of residues in honey (resulting from the residues in floral nectar), is the same as in primary and rotational crops. Further information, on whether enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues would be recommended (European Commission, 2018).

3.1.1. Analytical methods for enforcement in honey

For honey, an analytical method for the determination of pyrimethanil residues was submitted with the current application (Greece, 2022). The QuECHERS method in combination with LC–MS/MS is adequately validated for the detection of pyrimethanil residues in honey with a LOQ of 0.01 mg/kg. The method was validated with an independent laboratory validation (ILV) (Greece, 2022).

Since the existing guidance document on extraction efficiency (European Commission, 2023[10]) cannot be applied to the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, demonstration of extraction efficiency in honey matrix is not required for the present assessment.

3.1.2. Storage stability of residues in honey

A storage stability study of pyrimethanil in honey was not provided, however, as samples were frozen within 24 h after sampling and analysed within 17 days of sampling, this information is not required.

3.1.3. Proposed residue definitions

In the absence of specific metabolism studies on honey, the studies investigating the nature of pyrimethanil residues in primary and rotational crops and studies investigating the degradation of the active substance during hydrolysis are considered to derive the residue definitions for honey; the same residue definitions as mentioned for plant commodities (see Section 1.1.6) are therefore proposed.

3.2. Magnitude of residues in honey

In support of the MRL application, the applicant submitted four independent residue trials performed with a surrogate crop *Phacelia tanacetifolia* to investigate the residue transfer from treated plant to honey. Residue trials were performed in northern and southern European zones (Germany and Spain) under semi-field conditions during the growing season of 2020. The active substance was applied on *Phacelia tanacetifolia* (treated plot) three times at a rate of 1000 g a.s./ha with a 7-day ($\pm$ 2 days) interval. The first application was performed before the flowering of the crop (BBCH $<$ 61) and the following two applications at the flowering of the crop (BBCH 62–65).

The treatment regime applied in the tunnel trials was selected by the applicant as representative for the intended or authorised uses of pyrimethanil in Europe. The application rate tested in the residue trials is considered sufficiently representative of the worst-case GAP for residues in honey, as notified on melliferous crop in the context of this MRL application (i.e. SEU GAP on table grapes: 2 $\times$ 1000 g pyrimethanil/ha, 14 day-interval between applications, BBCH from 62 to 81, PHI of 21 days) (Greece, 2022).

Honey samples were collected when honey reached its commercial maturity (water content in honey from control and treated plots below 20%). The sampled amount was at least 100 g honey from treated replicates and control. Samples were analysed for pyrimethanil. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Greece, 2022). Storage stability study of pyrimethanil was not required, since all samples were analysed within 30 days. The residue levels in honey, measured as pyrimethanil, ranged from 0.016 to 0.107 mg/kg (Greece, 2022).

EFSA concluded that the residue trials were valid to derive an MRL proposal of 0.3 mg/kg for honey. It should be noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/621[11].

3.2.1. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for honey (see Appendix B.3.2.1). In Section 4, EFSA assessed whether residues in honey resulting from the intended and/or authorised uses of pyrimethanil on melliferous crops are likely to pose a consumer health risk.

[10] The previous revision 4 of SANTE/2017/10632, the technical guidance on extraction efficiency, was applicable at the date of submission of the IUCLID application (European Commission, 2022). Since then, further precisions on its applicability were addressed in the revised version 5, applicable from 23 May 2023. Since the revision 5 does not contain any new elements or obligations, EFSA took into consideration this newly released version directly.

[11] Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, pp. 1–73.

4. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for pyrimethanil used in the risk assessment were derived in the framework of the EU pesticides peer review (EFSA, 2006). For pyrimethanil, an acceptable daily intake (ADI) of 0.17 mg/kg bw per day was derived (European Commission, 2010b). A short-term exposure assessment is not required since the setting of an acute reference dose (ARfD) was considered not necessary (EFSA, 2006). EFSA notes that the toxicological assessment of pyrimethanil will be revised in the renewal of the approval process of pyrimethanil.

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed using EFSA PRIMo rev 2, taking into account the existing uses at the EU level and the acceptable CXLs (EFSA, 2011). EFSA updated this calculation using EFSA PRIMo rev.3.1, considering risk assessment values for several commodities as derived in the EFSA opinions published after the MRL review (EFSA, 2016a, 2018a). For the commodities under consideration and honey the STMR values as derived from the residue trials submitted in support of this MRL application were used as input values. In addition, STMR values for Codex MRLs taken over in the EU MRL legislation after the MRL review were included in the calculation (FAO, 2015; EFSA, 2016b). EFSA notes that the risk assessment residue definition for ruminant and swine commodities differs from the residue definition set for plants. For poultry commodities due to low dietary burdens no residues of pyrimethanil are expected and no residue definition for risk assessment has been established by the peer review or the MRL review. Poultry commodities were therefore not considered in the current risk assessment. The input values used in the exposure calculations are summarised in Appendix D.1.

Exceedances of the ADI are not indicated for any of the consumer groups. The highest estimated long-term dietary exposure is reported for the German child diet, representing up to 26% of the ADI of pyrimethanil. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is low and is presented in more detail in Appendix B.4.

The renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 is currently ongoing and the existing toxicological reference values might be revised. Thus, the conclusions reached for the consumer exposure assessment may need to be reconsidered in light of the outcome of the peer review for the renewal of the approval.

EFSA concluded that the long-term intake of residues of pyrimethanil resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

5. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for table grapes, garlic and honey.

EFSA concluded that the proposed use of pyrimethanil on table grapes and garlic as well as the intake of residues resulting from the potential transfer of residues of pyrimethanil into honey assessed in the present MRL application, will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

The renewal assessment of the active substance in accordance with Regulation (EC) No 1107/2009 is currently ongoing. The conclusions reported in this reasoned opinion may need to be reconsidered in light of the outcome of the peer review for the renewal of the approval.

The MRL recommendations are summarised in Appendix B.5.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CXL	Codex maximum residue limit
DAR	draft assessment report
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval

PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[c]	Number min-max	Interval between application (days) min-max	g a.s./ hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Table grapes	SEU (BG, EL IT, PT, ES)	F	*Botrytis cinerea* (BOTRCI)	SC	400 g/L	High volume spraying on foliage/plant	62–81	2	14	100–200	500–1000	1000	g a.s./ ha	21	
Garlic	SEU (BG, EL, IT, PT, ES)	F	*Botrytis* spp. (BOTRSP) *Sclerotium* spp. (SCLOSP)	SC	400 g/L	High volume spraying on foliage/plant	10–49	2	10–12	80–200	400–1000	800	g a.s./ ha	14	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1. Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Tomatoes	Foliar, G, 4 × 0.8 kg a.s./ha	Immediately after each treatment. Final sampling: 8	2-[U-^{14}C]-anilino and 2-[^{14}C]-pyrimidinyl labelled, (EFSA, 2006)
		Apples	Foliar treatment, 4 × 0.45 kg a.s./ha	42	
		Grapes	Foliar treatment (automatic pipette), 2 × 0.8 kg a.s./ha	21	2-[U-^{14}C]-anilino labelled, (EFSA, 2006)
	Root crops	Carrots	Foliar and soil treatment, 2 × 0.8 kg a.s./ha	1 and 21 days after the 1st and the 2nd treatment	The position of the labelling was not stated in the study report (Austria, 2005).
		Carrots	Foliar treatment, 2 × 2.4 kg a.s./ha	1 and 21 days after the 1st and the 2nd treatment	
	Leafy crops	Lettuce	Foliar treatment, F, 2 x 0.8 kg a.s./ha	Immediately after the first treatment, 7 and 21.	2-[^{14}C]-pyrimidinyl-labelled, (EFSA, 2006)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish	Bare soil application, G, 1 × 2.4 kg a.s./ha	30, 130, 300	2-[^{14}C]-pyrimidinyl-labelled Pyrimethanil (EFSA, 2006)
	Leafy crops	Lettuce			
	Cereal (small grain)	Wheat			
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2006)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		EFSA (2006)
	Sterilisation (20 min, 120°C, pH 6)		Yes		EFSA (2006)
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2006)
Rotational crop and primary crop metabolism similar?	No	The metabolic pathway is comparable in primary and rotational crops. However, metabolites were identified at levels equivalent or higher to that of the parent compound in rotational crops in contrast to primary crops. The metabolite found at the highest levels was C 621 312 (EFSA, 2006).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	
Plant residue definition for monitoring (RD-Mo)	Pyrimethanil (foliar treatment)	
Plant residue definition for risk assessment (RD-RA)	Pyrimethanil (foliar treatment)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water, high oil, high acid, high starch and high protein content: LC–MS/MS 0.01 mg/kg (EFSA, 2016a).	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; LC–MS/MS: liquid chromatography with tandem mass spectrometry.; F: Outdoor/field application; G: glasshouse/protected/indoor application

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High-water content	Apples	−18	24	Month	Pyrimethanil	EFSA (2016a)
	oil content	Rape seed	−20	12	Month	Pyrimethanil	EFSA (2006)
	High protein content	Dried peas	−20	12	Month	Pyrimethanil	EFSA (2006)
	High-acid content	Grapes	−18	12	Month	Pyrimethanil	EFSA (2006)

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Table grapes	SEU	**Mo:** 0.28; 0.55; 0.68; 0.75; 1.2; 1.7; 1.8; 3.55 **RA:** idem	Residue trials on grapevine compliant with GAP.	**6**	**Mo:** 3.55 **RA:** idem	**Mo:** 0.98 **RA:** idem	–
Garlic	SEU	**Mo:** 3 × < 0.010; 0.016 **RA:** idem	Residue trials on garlic compliant with GAP.	**0.03**	**Mo:** 0.016 **RA:** idem	**Mo:** 0.01 **RA:** idem	–

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	The amounts of pyrimethanil and its metabolites found in edible parts of the rotational crops sown or planted 30 days after ageing period were such that quantifiable residue levels can be expected (EFSA, 2006).
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	MRL review concluded that residual compounds resulting from the use of pyrimethanil in rotational crops is limited to low amounts and the resulting toxicological burden can be considered minor. Plant-back restriction was not deemed necessary (EFSA, 2011). Same conclusion is applicable for the present assessment, noting several deficiencies of the available field rotational crop study. The magnitude of residues in rotational crops is proposed to be reconsidered in the framework of the renewal of the approval of pyrimethanil taking into account all the European uses of the active substance.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application and are not required.

B.2. Residues in livestock

Not relevant.

B.3. Residues in honey

B.3.1. Nature of residues and analytical methods for enforcement purposes in honey

B.3.1.1. Metabolism studies, analytical methods and residue definitions in honey

Metabolism studies in honey	Metabolism studies in honey are not available. The nature of the residues in honey is based on the major components of the residue detected in primary crops, rotational crops and processed commodities.
Honey residue definition for monitoring (RD-Mo)	Pyrimethanil
Honey residue definition for risk assessment (RD-RA)	Pyrimethanil
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	QuECHERS method in combination with LC–MS/MS, LOQ of 0.01 mg/kg. The method was validated with an independent laboratory validation (ILV) (Greece, 2022).

QuECHERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.3.1.2. Storage stability of residues in honey

A storage stability study of pyrimethanil in honey was not provided, however, as samples were frozen within 24 h after sampling and analysed within 17 days of sampling, this information is not required.

B.3.2. Magnitude of residues in honey

B.3.2.1. Summary of residues data from the supervised residue trials

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/ Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Honey	SEU	**Mo:** 0.016; 0.034; 0.057; 0.107 **RA:** idem	Semi-field (tunnel) trials on *Phacelia tanacetifolia*. The number of trials is sufficient to derive an MRL in honey.	**0.3**	**Mo:** 0.107 **RA:** idem	**Mo:** 0.046 **RA:** idem	n.r.

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n.r.: not relevant.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.4. Consumer risk assessment

Acute exposure assessment not relevant since no ARfD has been considered necessary (EFSA, 2006).

ADI	0.17 mg/kg bw per day (European Commission, 2010b)
Highest IEDI, according to EFSA PRIMo	26% ADI (DE child diet) Highest contribution of crops assessed: Table grapes: 0.89% of ADI (NL toddler diet) Garlic: <0.1% of ADI (RO general diet) Honey: <0.1% of ADI (DE child diet)
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the median residue levels derived for raw agricultural commodities that would be expected according to the intended and authorised uses of pyrimethanil. The contributions of commodities where no GAP or no safe CXLs was reported in the framework of the MRL review and in the EFSA assessments following the MRL review were not included in the calculation (EFSA, 2011, 2014, 2016a,b, 2018a).

ARfD: acute reference dose; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; CXL: codex maximum residue limit; MRL: maximum residue level.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: pyrimethanil				
0151010	Table grapes	5	6	The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely.
0220010	Garlic	0.01*	0.03	The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely.
1040000	Honey and other apiculture products	0.05*	0.3	The submitted data are sufficient to derive a MRL proposal for honey. Risk for consumers unlikely.

MRL: maximum residue level; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Pyrimethanil

LOQs (mg/kg) range from: 0.01 to: 0.30

Toxicological reference values

ADI (mg/kg bw per day):	0.17	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acuterisk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculaton (based on average food consumption)	26%	DE child	44.36	12%	Apples	7%	Oranges	0.8%	Table grapes	0.2%	26%
	26%	NL toddler	43.53	10%	Apples	4%	Oranges	4%	Pears	0.3%	26%
	15%	NL child	25.51	5%	Apples	3%	Oranges	1%	Mandarins	0.3%	15%
	11%	FR child 3 15 yr	18.75	6%	Oranges	2%	Apples	0.4%	Wine grapes	0.4%	11%
	10%	DE women 14-50 yr	16.70	4%	Oranges	2%	Apples	0.9%	Wine grapes	0.2%	10%
	9%	IE adult	16.14	2%	Oranges	1%	Wine grapes	1%	Grapefruits	0.2%	9%
	9%	FR toddler 2 3 yr	15.73	3%	Apples	3%	Oranges	1%	Mandarins	0.3%	9%
	9%	DE general	14.89	3%	Oranges	2%	Apples	0.9%	Wine grapes	0.2%	9%
	9%	GEMS/Food G07	14.84	3%	Oranges	2%	Wine grapes	1.0%	Apples	0.3%	9%
	8%	ES child	14.08	4%	Oranges	1%	Apples	0.9%	Lettuces	0.3%	8%
	8%	UK toddler	13.56	4%	Oranges	2%	Apples	0.5%	Mandarins	0.2%	8%
	8%	GEMS/Food G06	12.88	2%	Oranges	0.9%	Apples	0.8%	Tomatoes	0.3%	8%
	7%	GEMS/Food G11	12.73	1%	Apples	1%	Oranges	1%	Wine grapes	0.3%	7%
	7%	PT general	12.46	3%	Wine grapes	1%	Oranges	1.0%	Apples	0.1%	7%
	7%	GEMS/Food G10	11.88	2%	Oranges	0.7%	Apples	0.7%	Lettuces	0.3%	7%
	7%	GEMS/Food G08	11.83	1%	Apples	1%	Wine grapes	0.9%	Oranges	0.3%	7%
	7%	SE general	11.19	1%	Oranges	1.0%	Apples	0.9%	Lettuces	0.4%	7%
	7%	ES adult	11.14	2%	Oranges	1%	Lettuces	0.7%	Apples	0.2%	7%
	7%	GEMS/Food G15	11.11	1%	Oranges	1%	Wine grapes	1%	Apples	0.3%	7%
	6%	NL general	10.49	2%	Oranges	1%	Apples	0.6%	Wine grapes	0.2%	6%
	6%	UK infant	10.09	2%	Oranges	1%	Apples	0.5%	Milk: Cattle	0.2%	6%
	6%	RO general	10.09	2%	Wine grapes	1%	Apples	0.5%	Oranges	0.2%	6%
	6%	FR adult	9.83	3%	Wine grapes	1%	Oranges	0.7%	Apples	0.2%	6%
	6%	DK child	9.36	2%	Apples	0.6%	Pears	0.3%	Oranges	0.5%	6%
	5%	IT toddler	8.56	0.9%	Oranges	0.8%	Apples	0.7%	Peaches	0.2%	5%
	5%	IT adult	7.89	0.8%	Lettuces	0.8%	Peaches	0.7%	Apples	0.1%	5%
	4%	UK vegetarian	7.58	2%	Oranges	0.9%	Wine grapes	0.6%	Apples	0.1%	4%
	4%	FI 3 yr	7.37	0.9%	Apples	0.7%	Mandarins	0.6%	Raspberries (red and yellow)	0.1%	4%
	4%	DK adult	6.48	1%	Wine grapes	0.9%	Apples	0.3%	Pears	0.2%	4%
	4%	UK adult	6.32	1%	Wine grapes	1%	Oranges	0.4%	Apples	0.1%	4%
	3%	FR infant	5.93	2%	Apples	0.5%	Oranges	0.3%	Mandarins	0.1%	3%
	3%	PL general	5.73	2%	Apples	0.3%	Pears	0.2%	Tomatoes		3%
	3%	FI 6 yr	5.71	0.6%	Mandarins	0.5%	Apples	0.5%	Raspberries (red and yellow)	0.1%	3%
	3%	FI adult	5.07	0.8%	Oranges	0.5%	Apples	0.3%	Wine grapes	0.0%	3%
	3%	LT adult	4.87	2%	Apples	0.1%	Pears	0.1%	Lettuces	0.2%	3%
	0.8%	IE child	1.39	0.3%	Apples	0.2%	Oranges	0.0%	Milk: Cattle	0.1%	0.8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyrimethanil is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Risk assessment residue definition for plant commodities: pyrimethanil						
Grapefruits	8	Existing MRL (EFSA, 2011)	3.14	STMR-RAC	Considering the toxicological profile of the active substance, an acute risk assessment was not needed as the setting of an ARfD for the active substance was considered not necessary (EFSA, 2006).	
Oranges	8	Existing MRL (EFSA, 2011)	3.14	STMR-RAC		
Lemons	8	Existing MRL (EFSA, 2011)	3.14	STMR-RAC		
Limes	8	Existing MRL (EFSA, 2011)	3.14	STMR-RAC		
Mandarins	8	Existing MRL (EFSA, 2011)	3.14	STMR-RAC		
Other citrus fruit	8	Existing MRL (EFSA, 2011)	3.14	STMR-RAC		
Almonds	0.2	Existing MRL (EFSA, 2011)	0.05	STMR-RAC		
Pistachios	0.2	Existing MRL (EFSA, 2011)	0.05	STMR-RAC		
Apples	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Pears	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Quinces	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Medlar	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Loquats/Japanese medlars	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Other pome fruit	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Apricots	10	Existing MRL (EFSA, 2011)	3.5	STMR-RAC		
Cherries (sweet)	4[b]	Existing MRL (FAO, 2007)	1.3	STMR-RAC		
Peaches	10	Existing MRL (EFSA, 2011)	3.5	STMR-RAC		
Plums	2	Existing MRL (EFSA, 2011)	0.48	STMR-RAC		
Table grapes	**6**	**MRL proposal**	**0.98**	**STMR-RAC (Table B.1.2.1)**		
Wine grapes	5	Existing MRL (EFSA, 2011)	1.86	STMR-RAC		
Strawberries	5	Existing MRL (EFSA, 2011)	1.15	STMR-RAC		
Blackberries	15[b]	Existing MRL (EFSA, 2016; FAO, 2015)	5.9	STMR-RAC		

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Raspberries (red and yellow)	15[b]	Existing MRL (EFSA, 2016; FAO, 2015)	5.9	STMR-RAC		
Blueberries	8[b]	Existing MRL (FAO, 2015)	2.1	STMR-RAC		
Cranberries	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Currants (red, black and white)	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Gooseberries (green, red and yellow)	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Rose hips	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Mulberries (black and white)	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Azarole/ Mediterranean medlar	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Elderberries	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Other small fruit & berries	5	Existing MRL (EFSA, 2011)	2	STMR-RAC		
Kaki/Japanese persimmons	15[b]	Existing MRL (FAO, 2013)	1.6	STMR-RAC		
Bananas	0.1	Existing MRL (EFSA, 2011)	0.05	STMR-RAC		
Potatoes	0.05	Existing MRL (EFSA, 2011)	0.05	STMR-RAC		
Carrots	1[b]	Existing MRL (FAO, 2007)	0.14	STMR-RAC		
Garlic	**0.03**	**MRL proposal**	**0.01**	**STMR-RAC (Table B.1.2.1)**		
Onions	0.2	Existing MRL (EFSA, 2011)	0.06	STMR-RAC		
Spring onions/ green onions and Welsh onions	3[b]	Existing MRL (FAO, 2007)	0.38	STMR-RAC		
Tomatoes	1	Existing MRL (EFSA, 2011)	0.36	STMR-RAC		
Sweet peppers/ bell peppers	2	Existing MRL (EFSA, 2011)	0.4	STMR-RAC		
Aubergines/ eggplants	1	Existing MRL (EFSA, 2011)	0.36	STMR-RAC		
Cucumbers	0.8	Existing MRL (EFSA, 2018)	0.24	STMR-RAC		
Gherkins	0.8	Existing MRL (EFSA, 2018)	0.24	STMR-RAC		

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Courgettes	0.8	Existing MRL (EFSA, 2018)	0.24	STMR-RAC		
Other cucurbits – edible peel	0.8	Existing MRL (EFSA, 2018)	0.24	STMR-RAC		
Lettuces	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Escaroles/broad-leaved endives	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Baby leaf crops (including brassica species)	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Chervil	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Chives	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Celery leaves	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Parsley	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Sage	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Rosemary	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Thyme	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Basil and edible flowers	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Laurel/bay leaves	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Tarragon	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Other herbs	20	Existing MRL (EFSA, 2011)	3.66	STMR-RAC		
Beans (with pods)	3[b]	Existing MRL (EFSA, 2011; FAO, 2007	0.23	STMR-RAC		
Peas (with pods)	3	Existing MRL (EFSA, 2011)	0.23	STMR-RAC		
Peas (without pods)	0.2	Existing MRL (EFSA, 2011)	0.07	STMR-RAC		
Leeks	4	Existing MRL EFSA, 2016	0.3	STMR-RAC		
Beans	0.5	Existing MRL (EFSA, 2011)	0.07	STMR-RAC		
Lentils	0.5	Existing MRL (EFSA, 2011)	0.07	STMR-RAC		
Peas	0.5	Existing MRL (EFSA, 2011)	0.07	STMR-RAC		

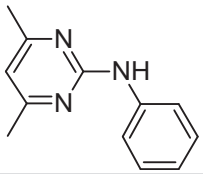
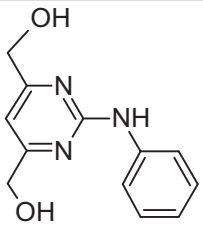
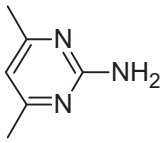
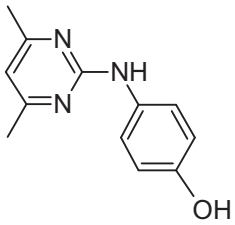
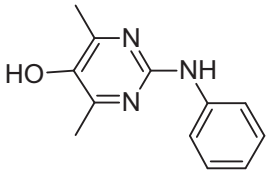
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment
Lupins/lupini beans	0.5	Existing MRL (EFSA, 2011)	0.07	STMR-RAC		
Barley	0.05*	Existing MRL (EFSA, 2011)	0.05	LOQ		
Oat	0.05*	Existing MRL (EFSA, 2011)	0.05	LOQ		
Rice	0.05*	Existing MRL (EFSA, 2011)	0.05	LOQ		
Rye	0.05*	Existing MRL (EFSA, 2011)	0.05	LOQ		
Wheat	0.05*	Existing MRL (EFSA, 2011)	0.05	LOQ		
Ginseng root	1.5[b]	FAO, 2013	0.41	STMR-RAC		
Honey and other apiculture products	**0.3**	**MRL proposal**	**0.046**	**STMR-RAC (Table B.3.2.1)**		
Risk assessment residue definition in animal tissue (except poultry): sum of pyrimethanil and 2-(4-hydroxyanilino)-4.6-dimethylpyrimidine (SN 614 276), expressed as pyrimethanil						
Swine: Muscle/ meat	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ	Considering the toxicological profile of the active substance, an acute risk assessment was not needed as the setting of an ARfD for the active substance was considered not necessary (EFSA, 2006).	
Swine: Fat tissue	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Swine: Liver	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Swine: Kidney	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Swine: Edible offals (other than liver and kidney)	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Swine: Other products	0.1*	Existing MRL	0.1	LOQ		
Bovine: Muscle/ meat	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Bovine: Fat tissue	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Bovine: Liver	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Bovine: Kidney	0.2	Existing MRL (EFSA, 2011)	0.17	STMR-RAC		
Bovine: Edible offals (other than liver and kidney)	0.1*	Existing MRL	0.1	LOQ		
Bovine: Other products	0.1*	Existing MRL	0.1	LOQ		
Sheep: Muscle/ meat	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Sheep: Fat tissue	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Sheep: Liver	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Sheep: Kidney	0.2	Existing MRL (EFSA, 2011)	0.17	STMR-RAC		
Sheep: Edible offals (other than liver and kidney)	0.1*	Existing MRL	0.1	LOQ		
Sheep: other products	0.1*	Existing MRL	0.1	LOQ		
Goat: Muscle/ meat	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Goat: Fat tissue	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Goat: Liver	0.1*	Existing MRL (EFSA, 2011)	0.1	LOQ		
Goat: Kidney	0.2	Existing MRL (EFSA, 2011)	0.17	STMR-RAC		
Goat: Edible offals (other than liver and kidney)	0.1*	Existing MRL	0.1	LOQ		
Goat: other products	0.1*	Existing MRL	0.1	LOQ		
Equine: Muscle/ meat	0.1*	Existing MRL	0.1	LOQ		
Equine: Fat tissue	0.1*	Existing MRL	0.1	LOQ		
Equine: Liver	0.1*	Existing MRL	0.1	LOQ		
Equine: Kidney	0.2	Existing MRL	0.17	STMR-RAC		
Equine: Edible offals (other than liver and kidney)	0.1*	Existing MRL	0.1	LOQ		
Equine: Other products	0.1*	Existing MRL	0.1	LOQ		
Other farmed animals: Muscle/ meat	0.1*	Existing MRL	0.1	LOQ		
Other farmed animals: Fat tissue	0.1*	Existing MRL	0.1	LOQ		
Other farmed animals: Liver	0.1*	Existing MRL	0.1	LOQ		
Other farmed animals: Kidney	0.2	Existing MRL	0.17	STMR-RAC		
Other farmed animals: Edible offals (other than liver and kidney)	0.1*	Existing MRL	0.1	LOQ		
Other farmed animals: Other products	0.1*	Existing MRL	0.1	LOQ		
Risk assessment residue definition in milk: sum of pyrimethanil and 2-anilino-4.6-dimethylpyrimidine-5-ol (SN 614 277), expressed as pyrimethanil						
Milk: Cattle	0.05*	Existing MRL (EFSA, 2011)	0.021	STMR-RAC		

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Milk: Sheep	0.05*	Existing MRL (EFSA, 2011)	0.021	STMR-RAC		
Milk: Goat	0.05*	Existing MRL (EFSA, 2011)	0.021	STMR-RAC		
Milk: Horse	0.05*	Existing MRL	0.021	STMR-RAC		
Milk: Others	0.05*	Existing MRL				

MRL: maximum residue level; STMR-RAC: supervised trials median residue in raw agricultural commodity; ARfD: acute reference dose; LOQ: limit of quantification.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.
(b): Existing MRL based on Codex MRL (CXL).

Appendix E – Used compound codes

Code/trivial name[(a)]	IUPAC name/SMILES notation/InChiKey[(b)]	Structural formula[(c)]
Pyrimethanil	*N*-(4,6-dimethylpyrimidin-2-yl)aniline Cc1cc(C)nc(Nc2ccccc2)n1 ZLIBICFPKPWGIZ-UHFFFAOYSA-N	
C 621 312 M605F005 AN5	(2-anilinopyrimidine-4,6-diyl)dimethanol OCc1cc(nc(Nc2ccccc2)n1)CO ZKEBQPCQWMBCSM-UHFFFAOYSA-N	
AE F132593 M605F007 ADMP	4,6-dimethylpyrimidin-2-amine Cc1cc(C)nc(N)n1 IDQNBVFPZMCDDN-UHFFFAOYSA-N	
SN 614 276 M605F002 AN2	4-[(4,6-dimethylpyrimidin-2-yl)amino]phenol Oc1ccc(cc1)Nc1nc(C)cc(C)n1 NUWWAHKTVOVTNC-UHFFFAOYSA-N	
SN 614 277 M605F003 AN3	2-anilino-4,6-dimethylpyrimidin-5-ol Cc1nc(Nc2ccccc2)nc(C)c1O YZWHZRWOWLGVQA-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).