Modification of the existing maximum residue level for pyrimethanil in cucurbits with edible peel

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Arysta LifeScience Benelux SPRL submitted a request to the competent national authority in Italy, to modify the existing maximum residue level (MRL) for the active substance pyrimethanil in cucurbits with edible peel. The data submitted in support of the request were found to be sufficient to derive a MRL proposal for cucurbits with edible peel. Adequate analytical methods for enforcement are available to control the residues of pyrimethanil on 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 short-term and 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.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Arysta LifeScience Benelux SPRL submitted an application to the competent national authority in Italy (evaluating Member State, EMS), to modify the existing maximum residue level (MRL) for the active substance pyrimethanil in cucurbits with edible peel. The EMS 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 the European Food Safety Authority (EFSA) on 1 June 2017. To accommodate for the intended use of pyrimethanil, the EMS proposed to raise the existing MRL from 0.7 mg/kg to 1.0 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

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 fruit crops, root crops and leafy crops. A confined rotational crop study was conducted on radish, lettuce and wheat following a bare soil application at a dose rate of 2,400 g a.s./ha. 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.

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

Based on these studies, the residue definitions for enforcement and risk assessment for plant products were proposed as pyrimethanil only for all categories of crops. For the use on cucurbits with edible peel, EFSA concludes that the metabolism of pyrimethanil in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

The available residue trials are sufficient to derive a MRL proposal of 0.8 mg/kg for cucurbits with edible peel. Adequate analytical enforcement methods are available to monitor the residues of pyrimethanil in these crops at the validated limit of quantification (LOQ) of 0.01 mg/kg.

Specific studies to assess the magnitude of pyrimethanil residues in processed commodities were not provided for cucurbits with edible peel. These studies are however not required for cucumbers since they are mostly eaten raw. For gherkins and courgettes (zucchini), studies investigating the impact of pasteurisation and cooking/boiling/baking on the residue concentration would be desirable, but are not indispensable, considering the low contribution of this crop to the total theoretical maximum daily intake (TMDI) (< 1% of the acceptable daily intake (ADI)).

The occurrence of pyrimethanil residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer review. Based on the available information, the possible presence of pyrimethanil residues in rotational crops cannot be fully excluded. However, the consumer exposure to the residues potentially present in rotational crops is expected to be low. The need to set a plant-back restriction should be considered in the framework of the renewal of the approval of pyrimethanil.

Residues of pyrimethanil in commodities of animal origin were not assessed since cucurbits with edible peel are normally not fed to livestock.

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.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMO. The total chronic intake accounted for up to 35% of the ADI (DE child). The contribution of residues in cucurbits with edible peel to the total consumer exposure accounted for less than 1% of the ADI.

EFSA concluded that the proposed use of pyrimethanil on cucurbits with edible peel will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health. EFSA proposes to amend the existing MRL as reported in the summary table below.

The peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.
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                                      |
|---------------|--------------------------------|-------------------------|-------------------------|------------------------------------------------------------|
| 0232000       | Cucurbits with edible peel     | 0.7                     | 0.8                     | The submitted data are sufficient to derive a MRL proposal for the greenhouse use. Risk for consumers is unlikely. |

**Enforcement residue definition**: Pyrimethanil

EU MRL: European Union maximum residue limit.

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

In accordance with Article 6 of Regulation (EC) No 396/2005, Arysta LifeScience Benelux SPRL submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance pyrimethanil in cucurbits with edible peel. The detailed description of the intended use of pyrimethanil on cucurbits with edible peel, which is the basis for the current MRL application, is reported in Appendix A.

The EMS 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 the European Food Safety Authority (EFSA) on 1 June 2017. To accommodate for the intended use of pyrimethanil, the EMS proposed to raise the existing MRL from 0.7 mg/kg to 1.0 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. In the course of detailed evaluation, EFSA asked for further clarifications which were provided by the EMS in an updated evaluation report submitted on 28 November 2017.

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2017), the draft assessment report (DAR) (and its addendum) (Austria, 2004, 2006) prepared under Council Directive 91/414/EEC, the Commission review report on pyrimethanil (European Commission, 2010c), the conclusion on the peer review of the pesticide risk assessment of the active substance pyrimethanil (EFSA, 2006) as well as the conclusions from previous EFSA opinions on pyrimethanil (EFSA, 2011, 2016).

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/EEC1 with Austria designated as rapporteur Member State (RMS) for the representative uses as a foliar spray application on grapes, apples and protein peas. The DAR prepared by the RMS (Austria, 2004, 2006) has been peer reviewed by EFSA (EFSA, 2006). Pyrimethanil was approved2 on 1 June 2007 for the use as fungicide only. The process of renewal of the first approval is currently ongoing.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/20053 (MRL review) has been completed (EFSA, 2011), and in 2014, the proposed modifications have been implemented in the European Union (EU) MRL legislation (Annex II of Regulation (EC) No 396/2005). Following the MRL review, EFSA has issued one reasoned opinion on the modification of the MRL in leek. The proposal from this reasoned opinion has been considered in recent regulations.4 In addition, certain Codex MRLs have been taken over in the EU legislation in 2015 and 2017.

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). 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 546/20116.

As the EU pesticides peer review for the renewal of approval of pyrimethanil in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application review, including the end points of relevant studies assessed previously and submitted in support of the current MRL application, are presented in Appendix B.

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1 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.
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, p. 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, 16.03.2005, p. 1-16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 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 Text with EEA relevance. OJ L 155, 11.6.2011, p. 1-66.
6 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
The evaluation report submitted by the EMS (Italy, 2017) 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.

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 fruit crops (tomatoes, apples and grapes), root crops (carrots) and leafy crops (lettuce) has been investigated in the framework of the EU pesticides peer review (EFSA, 2006). For the intended use, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Cucurbits with edible peel can be grown in rotation with other crops and the possible occurrence of residues of pyrimethanil and its metabolites in succeeding crops is required. During the EU pesticides peer review, a confined rotational crop study was conducted on radish, lettuce and wheat following a bare soil application at a dose rate of 2,400 g a.s./ha (EFSA, 2006). In contrast to the metabolism in primary crops, metabolites were identified at a level equivalent or higher than that of the parent compound. The metabolite generally present at highest levels was 2-anilino-4,6-dihydroxymethylpyrimidine (C 621 312). 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. Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable.

1.1.4. Methods of analysis in plants

In the framework of a previous MRL application, EFSA concluded that sufficiently validated analytical methods are available for the determination of pyrimethanil residues in high water-, high acid-, high oil-, high starch- and high protein-content commodities at a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2016).

1.1.5. Stability of residues in plants

Residues of pyrimethanil were found to be stable in high water- and high oil-content commodities at ≤ −18°C for 24 and 12 months, respectively (EFSA, 2016; France, 2016). In high acid-, high starch- and high protein-content commodities, stability of residues was shown for at least 12 months at ≤ −18°C (EFSA, 2006).

1.1.6. Proposed residue definitions

The peer review proposed pyrimethanil as the residue definition for enforcement and risk assessment (EFSA, 2006) which was confirmed by the MRL review (EFSA, 2011). The same residue definition is established in Regulation (EC) No 396/2005.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Eight Good Agricultural Practice (GAP) compliant residue trials on cucumbers performed in 2008 and 2009 in France, Spain, Greece and Italy were submitted in support of the MRL application. All trials are valid. All samples were analysed for the parent compound according to the agreed residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods
used were sufficiently validated for the determination of pyrimethanil residues in the crops under consideration. The samples of these residue trials were stored under conditions, for which integrity of the samples was demonstrated and it is concluded that the residue data are valid with regard to storage stability.

It is noted that in the framework of the MRL review, nine residue trials on cucumbers representative for the same GAP (residue trials performed in 1997 and 1998 under indoor conditions in Italy, Greece and Spain, application rate $3 \times 0.8$ kg/ha, preharvest interval (PHI) 3 days) were submitted and were used to derive the current MRL for cucurbits with edible peel (0.7 mg/kg). Considering that these are valid trials, it is proposed to combine the two data sets to derive the MRL proposal which in accordance with the current guidance document can be extrapolated to the whole group of cucurbits with edible peel (European Commission, 2017).

1.2.2. Magnitude of residues in rotational crops

The magnitude of pyrimethanil residues in rotational crops was investigated in the framework of the EU pesticides peer review (EFSA, 2006). In a field study conducted with a total dose rate of 1,600 g a.s./ha on lettuce as the target crop, no residues of pyrimethanil and of its main metabolite C621312 were found above the LOQ of the method (0.05 mg/kg) in the rotational crops (lettuce, brassica, wheat). It is noted that this field trial was conducted at a lower seasonal application rate compared to the intended use on cucurbits (0.7 N rate). Thus, provided that pyrimethanil is applied in compliance with the intended use on cucurbits with edible peel, the possible presence of pyrimethanil residues in rotational crops cannot be fully excluded. However, the consumer exposure to the residues potentially present in rotational crops is expected to be low. EFSA previous conclusion, that there is no need to set a plant-back restriction (EFSA, 2011), will be reconsidered in the framework of the renewal of the approval of pyrimethanil which 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 cucurbits with edible peel. These studies are however not required for cucumbers since they are mostly eaten raw. For gherkins and courgettes (zucchini), studies investigating the impact of pasteurisation and cooking/boiling/baking on the residue concentration would be desirable, but are not indispensable, considering the low contribution of this crop to the total theoretical maximum daily intake (TMDI) (< 1% of the acceptable daily intake (ADI)).

1.2.4. Proposed MRLs

The available residue trials are sufficient to derive a MRL proposal of 1 mg/kg for cucurbits with edible peel.

2. Residues in livestock

Not relevant as cucurbits with edible peel are not used for feed purposes.

3. Consumer risk assessment

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 bw per day. It was concluded that the establishment of an acute reference dose (ARfD) is not necessary (EFSA, 2006).

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (EFSA, 2007). In the framework of the Article 12 MRL review, a comprehensive long-term exposure assessment was performed for two scenarios:

- scenario B1: taking into account the existing uses in the EU,
- scenario B2: considering the EU uses and the acceptable Codex maximum residue limits (CXLs) (EFSA, 2011).

EFSA updated the risk assessment; for commodities with different supervised trials median residue (STMR) values used in scenarios B1 and B2, the most critical STMR value was selected. In addition, STMR values for Codex MRLs taken over in the EU MRL legislation after the MRL review were included.
in the calculation if they were higher than STMR values derived for EU GAPs. For cucurbits with edible peel, the STMR derived for the combined data set (residue trials assessed in the framework of the MRL review and the residue trials submitted in support of the current MRL application) is identical with the STMR used in 2011 (EFSA, 2011). The food commodities, for which no uses were reported in the framework of the Article 12 review, were excluded from the exposure calculation, assuming that there is no use of pyrimethanil on these crops.

The estimated exposure was then compared with the toxicological reference values derived for pyrimethanil. The result of the intake calculation using the EFSA PRIMO is a key supporting document and is made publicly available as a background document to this reasoned opinion.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMO. The highest calculated chronic intake was calculated to be 35% of the ADI (DE, child). The crops under assessment were minor contributors to the total ADI with a maximum of 0.23% of the ADI calculated for cucumbers.

EFSA concluded that the intended use of pyrimethanil on cucurbits with edible peel will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a concern for public health.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for the whole group of cucurbits with edible peel.

EFSA concluded that the proposed use of pyrimethanil on cucurbits with edible peel will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.

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Abbreviations

- a.s. active substance
- ADI acceptable daily intake
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CXL Codex maximum residue limit
- DAR draft assessment report
- DAT days after treatment
- EMS evaluating Member State
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- HR highest residue
- IEDI international estimated daily intake
- ISO International Organisation for Standardisation
- IUPAC International Union of Pure and Applied Chemistry
- 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 preharvest interval
- PRImo (EFSA) Pesticide Residues Intake Model
Modification of the existing MRL for pyrimethanil in cucurbits with edible peel

RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
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 | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-------------|--------------------------------|---------|
| Cucurbits with edible peel | EU | G | Grey mould: *Botrytis cinerea* (BOTRCI) | SC 400 g/L Spray application From preflowering (BBCH 59) up to PHI | 1–3 | 7 days | 80–133 | 600–1000 | 0.8 kg a.s./ha | 3 | 2 L Pyrus 400 SC/ha in 600 to 1,000 L water |

NEU: northern European Union; SEU: southern European Union; MS: Member State.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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 methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis 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-14C]-anilino and 2-[14C]-pyrimidinyl labelled, EFSA (2006) |
|                                   | Apples      | Foliar treatment, 4 × 0.45 kg a.s./ha | 42 | 2-[U-14C]-anilino and 2-[14C]-pyrimidinyl labelled, EFSA (2006) |
|                                   | Grapes      | Foliar treatment (automatic pipette), 2 × 0.8 kg a.s./ha | 21 | 2-[U-14C]-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 | EFSA (2006) |
|                                   | carrots     | Foliar treatment, 2 × 2.4 kg a.s./ha | 1 and 21 days after the 1st and the 2nd treatment | EFSA (2006) |
| Leafy crops                       | Lettuce     | Foliar treatment, F, 2 × 0.8 kg a.s./ha | Immediately after the first treatment, 7 and 21 | 2-[14C]-pyrimidinyl-labelled, EFSA (2006) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root crops                           | Radish      | Bare soil application, G, 1 × 2.4 kg a.s./ha | 30, 130, 300 | 2-[14C]-Pyrimidyl-labelled Pyrimethanil EFSA, 2006 |
| Leafy crops                          | Lettuce     | Bare soil application, G, 1 × 2.4 kg a.s./ha | 2-[14C]-Pyrimidyl-labelled Pyrimethanil, EFSA, 2006 |
| Cereal (small grain)                 | Wheat       | Bare soil application, G, 1 × 2.4 kg a.s./ha | 2-[14C]-Pyrimidyl-labelled Pyrimethanil, EFSA, 2006 |

| 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     |
| Question                                                                 | Yes                                                                 | No                                                                 |
|-------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|
| Can a general residue definition be proposed for primary crops?          |                                                                      | Metabolites were identified at levels equivalent or higher to that of the parent compound. The metabolite found at the highest levels was C 621 312 (EFSA, 2006) |
| Rotational crop and primary crop metabolism similar?                     |                                                                      |                                                                      |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? |                                                                      |                                                                      |
| Plant residue definition for monitoring (RD-Mo)                         | Pyrimethanil only for all categories of crops (foliar treatment)     |                                                                      |
| Plant residue definition for risk assessment (RD-RA)                    | Pyrimethanil only for all categories of crops (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 matrices: LC–MS/MS 0.01 mg/kg (EFSA, 2016) |                                                                      |
B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|-------------------|-----------|--------|------------------|-------------------|----------------|
|                                   | High water content| Apples    | –18    | 24 month         | Parent            | France, 2016   |
|                                   | High protein      | Dried peas| –20    | 12 month         | Parent            | EFSA, 2006     |
|                                   | High acid content | Grapes    | –20    | 12 month         | Parent            | EFSA, 2006     |
|                                   | High oil content  | Rape seed | –18    | 12 month         | Parent            | France, 2016   |

B.1.2. Magnitude of residues in plants

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

| Commodity                        | Region/Indoor(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) |
|----------------------------------|------------------|---------------------------------------------------------------|----------------|------------------------|---------------|-----------------|
| Cucurbits with edible peel       | G                | Mo: 0.10(d), 0.12, 0.12(d), 0.13, 0.16(d), 2 x 0.17, 0.19(d), 0.24(d), 0.25(d), 0.29(d), 0.32(d), 0.37(d), 0.38, 0.40, 0.46, 0.51 | Residue trials on cucumber compliant with GAP. Extrapolation to cucurbits with edible peel possible. | 0.8          | 0.51           | 0.24            |

MRL: maximum residue level.
(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.
(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): Residue trials submitted in the framework of the MRL review support of the indoor use on cucurbits (edible peel), (EFSA, 2011).
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 provided that pyrimethanil is applied according to the intended use on cucurbits with edible peel (EFSA, 2006)

Residues in rotational and succeeding crops expected based on field rotational crop study?
Inconclusive
The field study submitted in the framework of the peer review was under dosed (0.7 N) compared to the intended use on cucurbits with edible peel
The possible occurrence of quantifiable residues of pyrimethanil and its metabolites may occur in rotational crops

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application. Not required.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

Acute consumer risk assessment not relevant since no ARfD has been considered necessary.

| ADI | 0.17 mg/kg bw per day (EFSA, 2006) |
| Highest IEDI, according to EFSA PRIMO |
| 35% ADI (DE child) |
| Contribution of crops assessed: |
| Cucumber: 0.23% of ADI |
| Courgette: 0.1% of ADI |
| Gherkin: 0.03% of ADI |
| Assumptions made for the calculations |
| 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. The contributions of commodities where no use was reported or appropriately supported in the framework of the Article 12 MRL review (EFSA, 2011) were not included in the calculation |

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
| --- | --- | --- | --- | --- |
| 232000 | Cucurbits with edible peel | 0.7 | 0.8 | The submitted data are sufficient to derive a MRL proposal for the greenhouse use on cucurbits with edible peel. Risk for consumers is unlikely. |

MRL: maximum residue level.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Pyrimethanil

| Status of the active substance: | Included |
|--------------------------------|----------|
| Code no. | 001 Proposed PUG |

| Toxicological end points | ADI (mg/kg bw per day): | LOQ (mg/kg bw): | n.a. |
|--------------------------|-------------------------|----------------|------|
| Source of ADI | EFSA | Source of ARfD | EFSA |
| Year of evaluation | 2006 | Year of evaluation | 2006 |

- ADI (mg/kg bw per day): 0.17
- LOQ (mg/kg bw): 0.01

#### Source of ADI

- EFSA

#### Source of ARfD

- EFSA

#### Year of evaluation

- 2006

#### No of diets exceeding ADI

| TMDI (range in % of ADI) | No of diets exceeding ADI |
|--------------------------|---------------------------|
| Minimum – Maximum        | 4 – 35                     |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI values in % of ADI | pTMRLs at LOQ in % of ADI |
|-------------------------------|-------------------------|--------------------------|
| 35.4 DE child                 | 21.5 Apples             | 1.0 Oranges               |
| 23.4 NL child                 | 11.2 Apples             | 5.8 Oranges               |
| 11.9 IE adult                 | 1.9 Oranges             | 1.5 Apples                |
| 11.4 WHO Cluster diet B       | 1.0 Wine grapes         | 1.8 Apples                |
| 11.2 FR toddler               | 4.0 Apples              | 3.7 Oranges               |
| 9.2 ES child                  | 4.0 Oranges             | 2.0 Apples                |
| 9.2 UK Toddler               | 3.7 Oranges             | 5.0 Apples                |
| 8.3 FR infant                 | 4.4 Apples              | 1.7 Oranges               |
| 8.1 NL general               | 2.7 Oranges             | 2.1 Apples                |
| 8.1 PT General population    | 2.7 Wine grapes         | 1.9 Apples                |
| 7.9 FI all population         | 4.4 Wine grapes         | 0.8 Apples                |
| 7.2 ES adult                 | 2.4 Oranges             | 1.4 Apples                |
| 7.1 DK child                 | 4.1 Apples              | 0.6 Pears                 |
| 6.9 WHO cluster diet E       | 1.8 Wine grapes         | 1.5 Apples                |
| 6.7 UK infant                | 2.8 Apples              | 2.4 Oranges               |
| 6.3 SE general population 90th percentile | 1.9 Apples | 1.4 Oranges | 0.6 Mandarins |
| 5.8 WHO Cluster diet F       | 1.6 Oranges             | 1.2 Apples                |
| 5.6 IT kickstarter           | 1.6 Apples              | 0.9 Oranges               |
| 5.7 WHO regional European diet | 1.2 Apples             | 0.9 Oranges               |
| 5.3 IT adult                  | 1.4 Apples              | 0.8 Lettuce               |
| 5.2 PL general population     | 3.6 Apples              | 0.4 Table grapes          |
| 4.9 UK vegetable             | 1.6 Oranges             | 1.0 Apples                |
| 4.4 LT adult                 | 3.3 Apples              | 0.1 Pears                 |
| 4.3 WHO cluster diet D       | 1.2 Apples              | 0.4 Oranges               |
| 4.3 DK adult                 | 1.5 Wine grapes         | 1.4 Apples                |
| 4.0 UK adult                 | 1.2 Wine grapes         | 1.0 Oranges               |
| 3.6 FI adult                 | 1.8 Oranges             | 0.7 Apples                |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Pyrimethanil is unlikely to present a public health concern.

### Toxicological end points

#### Toxicological end points

- ADI (mg/kg bw per day): 0.17
- LOQ (mg/kg bw): 0.01

#### Source of ADI

- EFSA

#### Source of ARfD

- EFSA

#### Year of evaluation

- 2006

#### No of diets exceeding ADI

- 4 – 35

#### Highest calculated TMDI values in % of ADI

| Commodity/group of commodities | TMDI values in % of ADI | No of diets exceeding ADI |
|-------------------------------|-------------------------|---------------------------|
| 35.4 DE child                 | 21.5 Apples             | 1.0 Oranges               |
| 23.4 NL child                 | 11.2 Apples             | 5.8 Oranges               |
| 11.9 IE adult                 | 1.9 Oranges             | 1.5 Apples                |
| 11.4 WHO Cluster diet B       | 1.0 Wine grapes         | 1.8 Apples                |
| 11.2 FR toddler               | 4.0 Apples              | 3.7 Oranges               |
| 9.2 ES child                  | 4.0 Oranges             | 2.0 Apples                |
| 9.2 UK Toddler               | 3.7 Oranges             | 5.0 Apples                |
| 8.3 FR infant                 | 4.4 Apples              | 1.7 Oranges               |
| 8.1 NL general               | 2.7 Oranges             | 2.1 Apples                |
| 8.1 PT General population    | 2.7 Wine grapes         | 1.9 Apples                |
| 7.9 FI all population         | 4.4 Wine grapes         | 0.8 Apples                |
| 7.2 ES adult                 | 2.4 Oranges             | 1.4 Apples                |
| 7.1 DK child                 | 4.1 Apples              | 0.6 Pears                 |
| 6.9 WHO cluster diet E       | 1.8 Wine grapes         | 1.5 Apples                |
| 6.7 UK infant                | 2.8 Apples              | 2.4 Oranges               |
| 6.3 SE general population 90th percentile | 1.9 Apples | 1.4 Oranges | 0.6 Mandarins |
| 5.8 WHO Cluster diet F       | 1.6 Apples              | 1.2 Oranges               |
| 5.6 IT kickstarter           | 1.6 Apples              | 0.9 Oranges               |
| 5.7 WHO regional European diet | 1.2 Apples             | 0.9 Oranges               |
| 5.3 IT adult                  | 1.4 Apples              | 0.8 Lettuce               |
| 5.2 PL general population     | 3.6 Apples              | 0.4 Table grapes          |
| 4.9 UK vegetable             | 1.6 Oranges             | 1.0 Apples                |
| 4.4 LT adult                 | 3.3 Apples              | 0.1 Pears                 |
| 4.3 WHO cluster diet D       | 1.2 Apples              | 0.4 Oranges               |
| 4.3 DK adult                 | 1.5 Wine grapes         | 1.4 Apples                |
| 4.0 UK adult                 | 1.2 Wine grapes         | 1.0 Oranges               |
| 3.6 FI adult                 | 1.8 Oranges             | 0.7 Apples                |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Pyrimethanil is unlikely to present a public health concern.
Acute risk assessment/children – refined calculations

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 lead to an exposure equivalent to 100% of the ARfD.

* 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 Pyrimethanil residues is unlikely to present a public health concern.

| Commodities | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|--------------|---------------|----------------------|
| Highest % of ARfD/ADI | IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
| Processed commodities | | | | |
| Unprocessed commodities | | | | |

| Commodities | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|--------------|---------------|----------------------|
| Highest % of ARfD/ADI | IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
| Processed commodities | | | | |
| Unprocessed commodities | | | | |

| Commodities | pTMRL (mg/kg) | threshold MRL (mg/kg) |
|--------------|---------------|----------------------|
| Highest % of ARfD/ADI | IESTI 1 | IESTI 2 | IESTI 1 | IESTI 2 |
| Processed commodities | | | | |
| Unprocessed commodities | | | | |
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not applicable.

D.2. Consumer risk assessment

| Commodity                                             | Chronic risk assessment | Acute risk assessment                     |
|-------------------------------------------------------|-------------------------|-------------------------------------------|
|                                                       | Input value (mg/kg)     | Comment                                  | Input value (mg/kg)     | Comment                                  |
| Cucumber                                              | 0.24                    | STMR                                     |                            |                                          |
| Gherkins                                              | 0.24                    | STMR                                     |                            |                                          |
| Zucchini                                               | 0.24                    | STMR                                     |                            |                                          |
| Other cucurbits with edible peel                      | 0.24                    | STMR                                     |                            |                                          |
| Leek                                                  | 0.3                     | STMR (EFSA, 2016)                        |                            |                                          |
| Pears, quinces, medlars, loquats, azaroles, kaki      | 1.6                     | STMR (FAO, 2013)                         |                            |                                          |
| Blueberries                                           | 2.1                     | STMR (FAO, 2015)                         |                            |                                          |
| Ginseng                                                | 0.41                    | STMR (FAO, 2013)                         |                            |                                          |
| Other plant and animal commodities                    | STMR                    | See Table 4-1/4-2 in reasoned opinion on Article 12 MRL review (EFSA, 2011) |                            |                                          |

MRL: maximum residue level; STMR: supervised trials median residue.
## Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation\(^{(a)}\) | Structural formula\(^{(a)}\) |
|------------------|-----------------------------------------|-----------------------------|
| Pyrimethanil     | N-(4,6-dimethylpyrimidin-2-yl)aniline   | ![Pyrimethanil structural formula](image) |
|                  | Cc2cc(C)nc(Nc1cccc1)n2                 |                             |
|                  | MW: 199                                 |                             |
| C 621 312        | 4,6-dihydroxymethyl-N-phenylpyrimidin-2-amine | ![C 621 312 structural formula](image) |
|                  | OCc2cc(nc(Nc1cccc1)n2)CO               |                             |

\(^{(a)}\): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).